

GR



Original Submission

000004

AMERICAN

INGREDIENTS
COMPANY



February 23, 2000

Office of Premarket Approval

HFS-200

U. S. Food and Drug Administration

Center for Food Safety and Applied Nutrition

200 "C" Street, SW

Washington, DC 20004

Dear Sirs:

American Ingredients Company, of 3947 Broadway, Kansas City, Missouri, respectfully submits this GRAS Notification, pursuant to Section 170.30(b) of the Food Additive Regulations, with respect to the use of mineral oil. This GRAS Notification is being submitted to affirm as GRAS the use of mineral oil as an ingredient of a release agent sprayed on food-processing equipment, resulting in addition of mineral oil to food at no more than 5 parts per million (p.p.m.). Specifically, this notification affirms that the aforementioned use of mineral oil is GRAS based upon history of use. Because of this GRAS determination, we affirm this use of mineral oil is exempt from the premarket approval requirements of the Federal Food, Drug and Cosmetic Act.

The data and information that are the basis for our GRAS determination for this use of mineral oil are available for the Food and Drug Administration's review and copying at reasonable times at the address of American Ingredients Company noted previously, or the documents will be sent to FDA upon request.

With this GRAS notification, American Ingredients Company affirms that mineral oil is GRAS as an ingredient of a release agent sprayed on food processing equipment, and resulting in a presence on food at no more than 5.0 parts per million. This is similar to the approved use found in 21 CFR Section 172.878, which permits the use of white mineral oil as a bakery product release agent and lubricant, and also on raw fruits and vegetables as a protective coating (GMP levels). In bakery products its limit is at 0.15% of bakery product weight. Mineral oil also appears in the Secondary Direct Additives portion of the regulations, under 21 CFR Section 173.340, as a defoaming agent.

Sincerely,

AMERICAN INGREDIENTS COMPANY

000005

April Kates

Consultant for Regulatory Affairs

AK:jjl

Enclosures

11:28 FEB 28 2000

**GRAS NOTIFICATION
AMERICAN INGREDIENTS COMPANY**

GRAS Notification for Use of Mineral Oil as a Direct Additive in Food Products

Name of Notifier: **American Ingredients Company**

Post Office Address: 3947 Broadway
Kansas City, MO 64111
Telephone: 816-561-9050
Fax: 816-561-9909

Name of Notified Substance: Mineral Oil, USP

Conditions of Use: Mineral oil as an ingredient in a non-stick lubricant to be applied to food-processing equipment, such as moving belts, product chutes, and shakers.

Date: February 23, 2000

Submitted on behalf of American Ingredients Company by:

April F. Kates,
Consultant for Regulatory Affairs

000006

BLANK PAGE INSERTED FOR CORRECT PAGINATION



Computer Technology Services, Inc.

000007-
000009

**GRAS NOTIFICATION
AMERICAN INGREDIENTS COMPANY**

TABLE OF CONTENTS

	Page
A. Identity and Specifications	1
B. Method of Manufacture	1
C. Specifications for Food-Grade Mineral Oil	1
D. Stability of Mineral Oil	2
E. Intended Technical Effect and Use	2
F. Methodology for Analysis of Mineral Oil in Food	3
G. Consumer Exposure	4
H. Common Use Determinations	4
I. Environmental Assessment	7

000010

**GRAS NOTIFICATION
AMERICAN INGREDIENTS COMPANY**

APPENDICES

- I. Food Chemical Codex Monograph, 4th Edition (1996)
- II. 21 CFR 178.3620, Specifications for Food-Grade Mineral Oil
- III. Label for American Ingredients Nonstick Product Containing Mineral Oil
- IV. “White Mineral Oil in the Baking Industry,” by Raymond Bohn
- V. March 17, 1964 American Bakers Association Bulletin
- VI. Federal Register, December 1, 1998. FDA Final Rule on increased limit (800ppm) for Application of Mineral Oil to Raw Rice.
- VII. Regulatory Citations Pertaining to Mineral Oil in Food Products
- VIII. Analytic Laboratory Tests for Mineral Oil – References.
- IX. Abstracts of Recent Feeding Studies on Mineral Oil
- X. Hazardous Substances Databank entry for Mineral Oil

000011

**GRAS NOTIFICATION
AMERICAN INGREDIENTS COMPANY**

Name of Notifier: **American Ingredients Company**

Post Office Address: **3947 Broadway
Kansas City, MO 64111
Telephone: (816) 561-9909**

Name of Notified Substance: **Mineral Oil, USP**

000012

**GRAS NOTIFICATION
AMERICAN INGREDIENTS COMPANY**

A. Identity and Specifications

Formal Chemical Name: Mineral Oil, USP

Common Names, synonyms: Mineral Oil, White Mineral Oil, Paraffin Oil, Liquid Petrolatum

Chemical Abstracts Service Registry Number: 8012-95-1

Empirical Formula: Consists of a mixture of hydrocarbons from petroleum.

Structural Formula: Consists of a mixture of aliphatic , naphthalenic, and aromatic liquid hydrocarbons from petroleum.

Quantitative Composition: Mineral oil is a mixture of compounds.

Characteristic Properties: Colorless, oily liquid. Density, 0.83-0.86, Surface tension at 25 degrees is slightly below 35 dynes/cm. Insoluble in water, alcohol. Soluble in solvents such as benzene, ether, oils.

B. Method of Manufacture:

Mineral oil is made by refining cruder lubricating oils to remove unsaturated or volatile compounds. It is derived from naphthalenic or paraffinic distillates with sulfuric acid or through the use of hydrogenation. Hydrogenation eliminates aromatic amines and unsaturated compounds and removes all nitrogen and sulfur-containing components. Mineral oil consists mainly of saturated aliphatic and cyclic hydrocarbons.

C. Specifications for Food-Grade Mineral Oil:

Specifications for food-grade mineral oil are found in the Food Chemicals Codex IV, INS number 905(a) (Attachment 1). The tests that are referenced in FCC are those that are acceptable for specifications and identification. The tests include readily carbonizable substances, specific gravity, UV absorbance. Procedures are referenced.

Mineral oil also is listed in the U.S. Pharmacopoeia with specifications.

21 CFR 178.3620 also contains specifications and test methods used for mineral oil used as a component of nonfood articles intended for food-contact use. The analytical methods determine the ultraviolet absorbance limit, distillation specifications, and maximum pyrene content. See Attachment II.

000013

**GRAS NOTIFICATION
AMERICAN INGREDIENTS COMPANY**

D. Stability of Mineral Oil

Food-grade mineral oil is a relatively stable substance. It does not decompose with exposure to air, and it does not decompose unless heated to over 400 degrees F. Different mineral oil grades have different flash points and viscosities.

E. Intended Technical Effect and Use

The technical effect of the mineral oil is to prevent food products from sticking to food processing and conveying equipment. The mineral oil is mixed with other ingredients, but it comprises about 83% of the nonstick product. The other ingredients have approval for use as secondary direct additives in this application, as defoamers, or are considered GRAS. Product label is in Attachment III. The product is sprayed on the production line conveying equipment, including belts and shakers. The frequency of spraying, and the amount sprayed on the equipment will vary with the amount of equipment sprayed (line length) and the amount of product that passes over it. However, the use level on equipment is to be such that the maximum amount of mineral oil that would be present on food products would be 5.0 parts per million (p.p.m.).

Insofar as amount needed to achieve technical effect is concerned, instructions for use would be to spray the production equipment at a rate so as not to exceed the 5.0 p.p.m. of mineral oil on the food products. As previously stated, the amount and frequency of spraying the equipment would be dependent on the volume of product passing over the equipment. Labeling would read as found in Attachment III. The instructions would specify how to perform the calculation to determine the amount of lubricant that could be used. If use instructions were followed, maximum level in the food products should not exceed 5.0 p.p.m..

Limitations to Use and Fate in Food

There is no intended function of the mineral oil on the food surface. Its only function is as a nonstick agent in the spray product. There is a limitation to use. It is assumed that the fate of mineral oil on the surface of the food is that it will remain there. If too much of the product is applied to the production equipment, movement of the product over the equipment may be impaired (it may slip too much) or transfer of the mineral oil product to the food products will cause them to become oily and have a poor mouth feel and texture.

Mineral oil is insoluble in water, so any water vapor present which condenses in wrapped frozen food products will not wash the oil off the product. Degradation products probably will not

000014

**GRAS NOTIFICATION
AMERICAN INGREDIENTS COMPANY**

occur in the food product; on the production equipment there is little chance of degradation products forming, unless the equipment is subjected to extremely high heat levels (Mineral oil flashpoint is approximately 360° F.).

There is a reasonable chance that foods that contact the nonstick product will have some mineral oil on their surface. If these foods are then fried, the mineral oil will dissolve into the frying oil. Too much mineral oil could have deleterious effects on the frying oils used to cook the food products at the end user. The mineral oil could oxidize at the frying temperatures and cause the frying oil to degrade.

History of Use

Mineral oil has been used for many years as a lubricant in food product production. Its use predates 1958, and it is used presently in many food products and food-contact materials. An October 1960 article entitled, "White Mineral Oil in the Baking Industry," mentions that white mineral oil has been used in the baking industry since mechanical devices gained widespread use. It references a 1924 publication that refers to mineral oil a dough divider lubricant. (Attachments IV, V). A 1964 bulletin from the American Bakers Association discusses the FDA proposed regulation permitting the use of mineral oil in food. The article emphasized that it would be permitted in baked foods as a release agent and lubricant. The current approved use level is 0.15% of the weight of the baked goods. This is equivalent to 1500 parts per million, which is a much higher level than the 5.0 parts per million being proposed for this nonstick product. 5.0 parts per million would be equivalent to 0.0005% in food products. Mineral oil is also approved as a component of defoaming agents for wash water for sliced potatoes at not exceeding 0.008 percent of the wash water. This is equivalent to 80 parts per million, which is also higher than the level proposed for the nonstick substance for food processing equipment.

In December, 1998, the FDA amended the food additive regulations to increase to 0.08% (800 p.p.m.) the amount of mineral oil applied to rice as a dust-reducing agent.(See Attachment VI)

At present, FDA has sixteen 21 CFR regulatory citations for the use of mineral oil either as a direct human food additive, indirect food additive, or component of food contact packaging and labeling. These uses can be found in Attachment VII. At a minimum, the American public consumes a great deal of baked goods, and it is our assumption that many are at present consuming mineral oil with no deleterious effects.

F. Methodology for Analysis of Mineral Oil in Food

000015

There are several existing methods to analyze for mineral oil in food. These are referenced in Attachment VIII. To determine how much mineral oil has been added to food, an extraction

**GRAS NOTIFICATION
AMERICAN INGREDIENTS COMPANY**

would have to be performed. A sample of food product would be solvent-washed to extract any oils. The extract would then have to be then run through a gas chromatograph where the mineral oil fraction is determined and quantified.

G. Consumer Exposure

Foods that will be contacted by the mineral oil in the additive: All unpackaged food products conveyed on food equipment that is sprayed with the nonstick agent

Typical and maximum use levels: Maximum is 5.0 p.p.m., calculated based on weight of product passing over and contacting the equipment lubricant.

Population: The population exposed to the lubricant will be anyone consuming food products that are conveyed over food processing equipment that has been sprayed with this product. Examples include processed potatoes, raw fruit (oranges) after washing and waxing, frozen breaded poultry, and frozen food products.

Increase in consumption based on this GRAS notification: Increase in human consumption of food-grade mineral oil will be minimal because of the low amount (5.0 p.p.m.) being proposed as the maximum amount of mineral oil picked up by food products.

H. Common Use Determination

Detailed Summary of Information that are the Basis for This GRAS Determination (Common Use Data):

Technical evidence of safety:

As noted earlier, mineral oil has been used for many years in food product production, particularly in the baking industry. Its use predates 1958. An October 1960 article entitled, "White Mineral Oil in the Baking Industry," references a 1924 publication that refers to mineral oil as a dough divider lubricant.(Attachment IV). A 1964 bulletin from the American Bakers Association discusses the FDA proposed regulation permitting the use of mineral oil in food. The article emphasized that it would be permitted in baked foods as a release agent and lubricant.

Since that time, use of mineral oil has become widespread in many areas of food production. It is used to control dust on grains. The limit for raw rice (dust control) was raised to 800 p.p.m. in an FDA final rule in December 1998.

000016

**GRAS NOTIFICATION
AMERICAN INGREDIENTS COMPANY**

Current approvals for direct additive status for mineral oil (21 CFR 172.878) include its use as a release agent for capsules and tablets containing flavorings and spices, a release agent for bakery products, dehydrated fruits and vegetables, egg whites, yeast manufacture, confectionery manufacture. It is approved as a dust control agent for grains. It can be used as a defoamer in food, and a protective coating on raw fruits and vegetables.

With these approved uses, mineral oil has been ingested by a significant number of consumers for a very long time. From the literature review done with this GRAS notification, no data was found that indicated any reason to doubt the safety of mineral oil from all current approved uses. There were no studies found that indicate adverse effects from using mineral oil in any of its approved food additive uses.

There have been many studies over the years pertaining to mineral oil. A review of the literature was conducted on Toxline. Results are in Attachment IX. A summary of the results follows.

Generally, there are many studies indicating that mineral oil consumed in large quantities over time causes mal-absorption of nutrients, digestive problems, and if inhaled into lungs, lipoid pneumonia. However, at the low levels being requested in this GRAS notification, there is little question that these adverse health effects will not be experienced.

In 1991 the American Conference of Governmental Industrial Hygienists published a study where three groups of 30 rats received 2% liquid paraffin (mineral oil) in the diet, and no significant tumor induction was found.¹ The dosing period was 500 days. Another 1991 published study by the same group found no treatment-related tumor increase when three grades of mineral oil were fed at a concentration of 5% in the diet to groups of 50 male and 50 female rats for 2 years.²

There are several recent animal feeding studies conducted with mineral oil. (See Attachment IX). These studies were published and are publicly available through the National Library of Medicine's Grateful Med. They are summarized below:

The first study was published in 1992. In it, male or female Fischer-344 rats were fed either oleum-treated white oil or hydrotreated white oil, to determine the effects, and difference between the effects of these two different oil treatments on rats. The study results were that any

000017

¹ American Conference of Governmental Industrial Hygienists. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th Ed. Vol. I, II, III, Cincinnati, OH ACGIH, 1991

² Ibid.

**GRAS NOTIFICATION
AMERICAN INGREDIENTS COMPANY**

effects were generally related to the dosage fed the rats, rather than by the way the oil was treated. Female rats showed more changes than males. Changes in hepatic tissues, chemistry or function were found in rats fed 5000 p.p.m. or more of the oils. The 10 and 100 p.p.m. feeding levels showed no changes and these correspond to 0.64 and 6.4 mg/kg/day.

The next study was published in 1995. This was a 90-day feeding study of Long-Evans rats and beagle dogs fed 4 different white mineral oils. The study purpose was to determine the toxicity of the oils. Levels fed were 300 and 1500 p.p.m. There were no toxicological treatment- related effects.

Another study published in 1995 was a comparative 90-day feeding study with low-viscosity white mineral oil in Fischer-344 and Sprague-Dawley-derived rates. The study found that the Fischer-344 rats are far more sensitive to the presence of mineral hydrocarbons in their diet than the Sprague-Dawley rats. The Fischer rats showed hepatic and mesenteric microgranulomas, while the other rats did not.

In 1996 there was a toxicological review of topical exposure to white mineral oils. Repeated topical exposure was found not to produce any toxicological effects in Fischer 344 rats, C3H mice, New Zealand white rabbits or beagles at exposure rates similar to the ingestion studies.

In 1996 there was a published 90-day feeding study of seven white oils and 5 waxes fed to Fischer 344 rats. Dietary doses were 20,000, 2,000, 200 and 20 p.p.m. and were compared with a control group. Reversal periods were also studied. Effects were found mostly in liver and mesenteric lymph nodes, and in females more than males. Paraffin waxes were found to affect the cardiac mitral valve.

Finally, in 1998 a published study compared granulomas in the livers of human and Fischer rats, both associated with mineral oil ingestion. The study concludes that the majority of the lesions induced in rats are of no significance for humans, and the human lesions are not believed to progress to clinically significant lesions.

In general, all the above-referenced studies did not raise any major questions about the affect of mineral oil on humans, certainly not at lower dosages. In general the effect of feeding mineral oil to rats resulted in deposits in the liver and/or mesenteric lymph nodes. In some cases, the effects were reversed when mineral oil was removed from the diet. There were differences between rat species, and the pathologic responses differences were attributed to differing sensitivities of the species. No significant toxic effects were induced in beagle dogs.

The review of the literature did not result in finding any information about adverse health effects from the current approved food uses of mineral oil. No published studies were found documenting adverse health effects due to the use of mineral oil as a release agent in baked

000018

**GRAS NOTIFICATION
AMERICAN INGREDIENTS COMPANY**

goods. This specific use is cited because it is similar to the use of mineral oil in this GRAS notification. The current use of mineral oil in food is widespread. If there were any adverse effects from the widespread use they would surely be reported.

Appendix X is mineral oil information downloaded from the Hazardous Substances Databank of the National Library of Medicine. While there appears to be a lot of information regarding health effects of inhalation or over-consumption of mineral oil (for medical effects), there was none implying health problems related to the use of mineral oil as a lubricant or release agent in food production.

I. Environmental Assessment

In accordance with 21 CFR Sections 25.32(f) and 25.32(k), no environmental assessment is being provided with this Petition because a categorical exclusion applies to the requested use of mineral oil. No environmental assessment is required because it is affirmed as GRAS, and is a prior-sanctioned food additive. Under 25.32(k), mineral oil could also be considered a direct additive, and thus considered to be added directly to food, is intended to remain on the food through human ingestion, and is not intended to replace any macronutrients in food.

.....

000019

02/23/00

Page 8

**GRAS NOTIFICATION
AMERICAN INGREDIENTS COMPANY**

.....

In consideration of the foregoing and all appendices to this GRAS Notification, it is requested that the Food and Drug Administration review these materials and agree with our conclusion that for the purpose as an ingredient of a nonstick spray product, mineral oil is GRAS AT 5.0 parts per million.

Respectfully submitted,

AMERICAN INGREDIENTS COMPANY

000020

Pages 0000021 - 0000022 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

§ 178.3620

21 CFR Ch. I (4-1-98 Edition)

which it contacts food does not exceed 0.002 inch.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 54 FR 24898, June 12, 1989]

§ 178.3620 Mineral oil.

Mineral oil may be safely used as a component of nonfood articles intended for use in contact with food, subject to the provisions of this section:

(a) White mineral oil meeting the specifications prescribed in § 172.878 of this chapter may be used as a component of nonfood articles provided such use complies with any applicable limitations in parts 170 through 189 of this chapter. The use of white mineral oil in or on food itself, including the use of white mineral oil as a protective coating or release agent for food, is subject to the provisions of § 172.878 of this chapter.

(b) Technical white mineral oil identified in paragraph (b)(1) of this section may be used as provided in paragraph (b)(2) of this section.

(1) Technical white mineral oil consists of specially refined distillates of virgin petroleum or of specially refined distillates that are produced synthetically from petroleum gases. Technical white mineral oil meets the following specifications:

(i) Saybolt color 20 minimum as determined by ASTM method D156-82, "Standard Test Method for Saybolt Color of Petroleum Products (Saybolt Chromometer Method)," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(ii) Ultraviolet absorbance limits as follows:

Wavelength (mμ)	Maximum absorbance per centimeter optical pathlength
280 to 289	4.0
290 to 299	3.3
300 to 329	2.3
330 to 350	0.8

Technical white mineral oil containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application to mineral oil under "Specification" on page 66 of the "Journal of the Association of Official Agricultural Chemists," Volume 45 (February 1962) (which is incorporated by reference; copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408), disregarding the last two sentences of that procedure and substituting therefor the following: Determine the absorbance of the mineral oil extract in a 10-millimeter cell in the range from 260-350 mμ, inclusive, compared to the solvent control. If the absorbance so measured exceeds 2.0 at any point in range 280-350 mμ, inclusive, dilute the extract and the solvent control, respectively, to twice their volume with dimethyl sulfoxide and remeasure the absorbance. Multiply the remeasured absorbance values by 2 to determine the absorbance of the mineral oil extract per centimeter optical pathlength.

(2) Technical white mineral oil may be used wherever mineral oil is permitted for use as a component of nonfood articles complying with §§ 175.105, 176.200, 176.210, 177.2260, 177.2600, and 177.2800 of this chapter and §§ 178.3570 and 178.3910.

(3) Technical white mineral oil may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

(c) Mineral oil identified in paragraph (c)(1) of this section may be used as provided in paragraph (c)(2) of this section.

(1) The mineral oil consists of virgin petroleum distillates refined to meet the following specifications:

(i) Initial boiling point of 450 °F minimum.

(ii) Color 5.5 maximum as determined by ASTM method D1500-82, "Standard

Test Method for ASTM Color of Petroleum Products (ASTM Color Scale)," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(1) of this section.

(iii) Ultraviolet absorbance limits as follows as determined by the analytical method described in paragraph (c)(3) of this section:

Wavelength (mμ)	Maximum absorbance per centimeter optical pathlength
280 to 289	0.7
290 to 299	0.6
300 to 359	0.4
360 to 400	.09

(2) The mineral oil may be used wherever mineral oil is permitted for use as a component of nonfood articles complying with §§175.105 and 176.210 of this chapter and §178.3910 (for use only in rolling of metallic foil and sheet stock), §§176.200, 177.2260, 177.2600, and 177.2800 of this chapter.

(3) The analytical method for determining ultraviolet absorbance limit is as follows:

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of oil samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir. 500-milliliter capacity, equipped with a 24/40 standard taper male fitting at the bottom and a suitable ball-joint at the

top for connecting to the nitrogen supply. The male fitting should be equipped with glass hooks.

Chromatographic tube. 180 millimeters in length, inside diameter to be 15.7 millimeters ± 0.1 millimeter, equipped with a coarse, fritted-glass disc, a tetrafluoroethylene polymer stopcock, and a female 24/40 standard tapered fitting at the opposite end. (Overall length of the column with the female joint is 235 millimeters.) The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2-inch diameter disk approximately $\frac{1}{8}$ -inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Suction flask. 250-milliliter or 600-milliliter filter flask.

Condenser. 24/40 joints, fitted with a drying tube, length optional.

Evaporation flask (optional). 250-milliliter or 500-milliliter capacity all-glass flask equipped with standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5,000 centimeter ± 0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1,000 centimeter ± 0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons—400 millimicrons with spectral slit width of 2 millimicrons or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ± 0.01 at 0.4 absorbance.

Absorbance accuracy¹ ± 0.05 at 0.4 absorbance.

Wavelength accuracy, ± 1.0 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

¹As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, acetone, and methyl alcohol designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and *n*-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 25 milliliters volume. Determine the absorbance in the 5-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimeter path length between 280 and 400 mμ. For methyl alcohol this absorbance value shall be 0.00.

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Company, Baltimore, Maryland, or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

Benzene, A.C.S. reagent grade. Use 150 milliliters for the test. Purify, if necessary, by distillation or otherwise.

Acetone, A.C.S. reagent grade. Use 200 milliliters for the test. Purify, if necessary, by distillation.

Eluting mixtures:

1. **10 percent benzene in isooctane.** Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask and adjust to volume with isooctane, with mixing.

2. **20 percent benzene in isooctane.** Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask and adjust to volume with isooctane, with mixing.

3. **Acetone-benzene-water mixture.** Add 20 milliliters of water to 380 milliliters of acetone and 200 milliliters of benzene, and mix.

***n*-Hexadecane, 99-percent olefin-free.** Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference point between 280 mμ-400 mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Methyl alcohol, A.C.S. reagent grade. Use 10.0 milliliters of methyl alcohol. Purify, if necessary, by distillation.

Dimethyl sulfoxide. Spectrophotometric grade (Crown Zellerbach Corporation, Camas, Washington, or equivalent). Absorbance (1-centimeter cell, distilled water reference, sample completely saturated with nitrogen).

Wavelength	Absorbance (maximum)
281.5	1.00
270	.20
275	.09
280	.06
300	.015

There shall be no irregularities in the absorbance curve within these wavelengths.

Phosphoric acid, 85 percent A.C.S. reagent grade.

Sodium borohydride, 98 percent.

Magnesium oxide (Sea Sorb 43, Food Machinery Company, Westvaco Division, distributed by chemical supply firms, or equivalent). Place 100 grams of the magnesium oxide in a large beaker, add 700 milliliters of distilled water to make a thin slurry, and heat on a steam bath for 30 minutes with intermittent stirring. Stir well initially to insure that all the adsorbent is completely wetted. Using a Buchner funnel and a filter paper (Schleicher & Schuell No. 597, or equivalent) of suitable diameter, filter with suction. Continue suction until water no longer drips from the funnel. Transfer the adsorbent to a glass trough lined with aluminum foil (free from rolling oil). Break up the magnesia with a clean spatula and spread out the adsorbent on the aluminum foil in a layer about 1 centimeter to 2 centimeters thick. Dry for 24 hours at 160 °C ± 1 °C. Pulverize the magnesia with mortar and pestle. Sieve the pulverized adsorbent between 60-180 mesh. Use the magnesia retained on the 180-mesh sieve.

Celite 545, Johns Mansville Company, diatomaceous earth, or equivalent.

Magnesium oxide-Celite 545 mixture (2+1) by weight. Place the magnesium oxide (60-180 mesh) and the Celite 545 in 2 to 1 proportions, respectively, by weight in a glass-stoppered flask large enough for adequate mixing. Shake vigorously for 10 minutes. Transfer the mixture to a glass trough lined with aluminum foil (free from rolling oil).

and spread it out on a layer about 1 centimeter to 2 centimeters thick. Reheat the mixture at $160^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 2 hours, and store in a tightly closed flask.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter course, fritted-glass funnel or in a 65-millimeter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter path length between 280 m μ and 400 m μ when tested as prescribed under "Organic solvents." Usually three portions of wash solvent are sufficient.

Before proceeding with analysis of a sample, determine the absorbance in a 5-centimeter path cell between 250 millimicrons and 400 millimicrons for the reagent blank by carrying out the procedure, without an oil sample, recording the spectra after the extraction stage and after the complete procedure as prescribed. The absorbance per centimeter pathlength following the extraction stage should not exceed 0.02 in the wavelength range from 280 m μ to 400 m μ ; the absorbance per centimeter pathlength following the complete procedure should not exceed 0.02 in the wavelength range from 280 m μ to 400 m μ . If in either spectrum the characteristic benzene peaks in the 250 m μ -260 m μ region are present, remove the benzene by the procedure under "Organic solvents" and record absorbance again.

Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isooctane and shake to pre-equilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

Weigh a 20-gram sample of the oil and transfer to a 500-milliliter separatory funnel containing 100 milliliters of pre-equilibrated sulfoxide-phosphoric acid mixture. Complete the transfer of the sample with small portions of pre-equilibrated isooctane to give a total volume of the oil and solvent of 75 milliliters. Shake the funnel vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of pre-equilibrated isooctane. After separation of liquid phases, carefully draw off lower layer into the first 250-milliliter separatory funnel and wash in tandem with the 30-milliliter portions of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1

minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture and wash each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter) containing 480 milliliters of distilled water; mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 80-milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see Sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Quantitatively transfer the residue with isooctane to a 200-milliliter volumetric flask, make to volume, and mix. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to isooctane as reference between 280 m μ -400 m μ (take care to lose none of the solution in filling the sample cell). Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without an oil sample. If the corrected absorbance does not exceed the limits prescribed in this paragraph, the oil meets the ultraviolet absorbance specifications. If the corrected absorbance per centimeter pathlength exceeds the limits prescribed in this paragraph, proceed as follows: Quantitatively transfer the isooctane solution to a 125-milliliter flask equipped with 24/40 joint, and evaporate the isooctane on the steam bath under a stream of nitrogen to a volume of 1 milliliter of hexadecane. Add 10 milliliters of methyl alcohol and approximately 0.3 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere. A measuring dipper may be

used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the borohydride is dissolved, and allow to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this period, disconnect the flask and evaporate the methyl alcohol on the steam bath under nitrogen until the sodium borohydride begins to come out of the solution. Then add 10 milliliters of isooctane and evaporate to a volume of about 2-3 milliliters. Again, add 10 milliliters of isooctane and concentrate to a volume of approximately 5 milliliters. Swirl the flask repeatedly to assure adequate washing of the sodium borohydride residues.

Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weigh out 14 grams of the 2:1 magnesium oxide-Celite 545 mixture and pour the adsorbent mixture into the chromatographic tube in approximately 3-centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. Loosen the topmaforementioned rate. Just before the solvent mixture reaches adsorbent level, add 25 milliliters of 20 percent benzene in isooctane to the reservoir and continue the percolation at 2-3 milliliters per minute until all this solvent mixture has been removed from the column. Discard all the elution solvents collected up to this point. Add 300 milliliters of the acetone-benzene-water mixture to the reservoir and percolate through the column to eluate the polynuclear compounds. Collect the eluate in a clean 1-liter separatory funnel. Allow the column to drain until most of the solvent mixture is removed. Wash the eluate three times with 300-milliliter portions of distilled water, shaking well for each wash. (The addition of small amounts of sodium chloride facilitates separation.) Discard the aqueous layer after each wash. After the final separation, filter the residual benzene through anhydrous sodium sulfate pre-washed with benzene (see Sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the separatory funnel with two additional 20-milliliter portions of benzene which are also filtered through the sodium sulfate. Add 1 milliliter of *n*-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under "Organic solvents." Quantitatively transfer the residue with isooctane to a 200-milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to

isooctane as reference between 250 mμ-400 mμ. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without an oil sample. If either spectrum shows the characteristic benzene peaks in the 250 mμ-280 mμ region, evaporate the solution to remove benzene by the procedure under "Organic solvents." Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 200-milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits proposed in this paragraph, the oil meets the proposed ultraviolet absorbance specifications.

(d) Mineral oil identified in paragraph (d)(1) of this section may be used as provided in paragraph (d)(2) of this section.

(1) The mineral oil consists of virgin petroleum distillates refined to meet the following specifications:

(i) Distillation endpoint at 760 millimeters pressure not to exceed 371 °C, with a maximum residue not to exceed 2 percent, as determined by ASTM method D86-82, "Standard Method for Distillation of Petroleum Products," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section.

(ii) Ultraviolet absorbance limits as follows as determined by the method described in paragraph (d)(3) of this section.

Wavelength (mμ)	Maximum absorbance per centimeter optical pathlength
280 to 299	2.3
300 to 319	1.2
320 to 359	.8
360 to 400	.3

(iii) Pyrene content not to exceed a maximum of 25 parts per million as determined by the method described in paragraph (d)(3) of this section.

(2) The mineral oil may be used only in the processing of jute fiber employed in the production of textile bags intended for use in contact with the following types of food: Dry grains and dry seeds (for example, beans, peas, rice, and lentils); whole root crop vegetables of the types identified in 40 CFR 180.34(f); unshelled and shelled nuts (including peanuts); and dry animal feed. The finished processed jute fiber shall

contain no more than 6 percent by weight of residual mineral oil.

(3) The analytical method for determining ultraviolet absorbance limits and pyrene content is as follows:

I. *Apparatus*. A. Assorted beakers, separatory funnels fitted with tetrafluoroethylene polymer stopcocks, and graduated cylinders.

B. Volumetric flasks, 200-milliliter.

C. A chromatographic column made from nominal 1.3 centimeters outside diameter \times 75 centimeters glass tubing tapered at one end and joined to a 2-millimeter-bore tetrafluoroethylene polymer stopcock. The opposite end is flanged and joined to a female 24/40 standard taper fitting. This provides for accommodating the 500-milliliter reservoir described in item I.E below.

D. A chromatographic column made from nominal 1.7 centimeters outside diameter \times 115 centimeters glass tubing tapered at one end and joined to a 2-millimeter-bore tetrafluoroethylene polymer stopcock. The opposite end is flanged and joined to a 2.5 centimeters outside diameter \times 9.0 centimeters glass tube having a female 24/40 standard taper fitting. This provides for accommodating the 500-milliliter reservoir described in item I.E below.

E. A 500-milliliter reservoir having a 24/40 standard taper male fitting at bottom and a suitable ball joint at the top for connecting to the nitrogen supply. The female fitting of the chromatographic columns described in items I.C and D above and the male fitting of the reservoir described in this item E should both be equipped with glass hooks.

(NOTE: Rubber stoppers are not to be used. Stopcock grease is not to be used on ground-glass joints in this method.)

F. A spectrophotometer equipped to automatically record absorbance of liquid samples in 1-centimeter pathlength cells in the spectral region of 280–400 m μ with a spectral slit width of 2 m μ or less. At an absorbance level of about 0.4, absorbance measurements shall be repeatable within ± 0.01 and accurate within ± 0.05 . Wavelength measurements shall be repeatable with ± 0.2 m μ and accurate within ± 1.0 m μ . Instrument operating conditions are selected to realize this performance under dynamic (automatic) recording operations. Accuracy of absorbance measurements are determined at 290, 345, and 400 m μ , using potassium chromate as the reference standard. (National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, 1949.)

G. Two fused quartz cells having pathlengths of 1.00 \pm 0.005 centimeter or better.

II. *Purity of reagents and materials*. Reagent-grade chemicals shall be used in all tests. It is further specified that each chemical shall

be tested for purity in accordance with the instruction given under "Reagents and Materials" in III below. In addition, a blank run by the procedure shall be made on each purified lot of reagents and materials. Unless otherwise indicated, references to water shall be understood to mean distilled water.

III. *Reagents and materials*—A. *Organic solvents*. All solvents used throughout the procedure shall meet the specifications and tests described in this section III. The isooctane, benzene, cyclohexane, nitromethane, and *n*-hexadecane designated shall pass the following test: To the specified quantity of solvent in a 150-milliliter beaker, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains (to the residue from benzene and nitromethane add a 10-milliliter portion of purified isooctane, re-evaporate, and repeat once to insure complete removal of solvent). Dissolve the 1 milliliter of *n*-hexadecane residue in isooctane and make to 10-milliliter volume. Determine the absorbance in 1.0-centimeter pathlength cells compared to water as reference. The absorbance of the solution of solvent residue shall not exceed 0.05 between 280 and 400 m μ .

1. *Isooctane* (2,2,4-trimethylpentane). Use 240 milliliters for the above test. Purify, if necessary, by passage through a column of activated silica gel.

2. *Benzene*. Use 200 milliliters for the above test. Purify, if necessary, by distillation or otherwise.

3. *Cyclohexane*. Use 70 milliliters for the above test. Purify, if necessary, by distillation, silica gel percolation, or otherwise.

4. *Nitromethane*. Use 125 milliliters for the above test. Purify, if necessary, by distillation or otherwise.

5. *n-Hexadecane*. Determine the absorbance on this solvent directly. Purify, if necessary, by silica gel percolation or otherwise.

B. *Other materials*—1. *Pyrene standard reference*. Pyrene, reagent grade, melting point range 150–152 °C. (Organic Chemical 3627, Eastman Kodak Co., Rochester, N.Y., or equivalent). The standard reference absorbance is the absorbance at 334 millimicrons of a standard reference solution of pyrene containing a concentration of 1.0 milligram per liter in purified isooctane measured against isooctane of the same spectral purity in 1.0-centimeter cells. (This absorbance will be approximately 0.28.)

2. *Chrysene solution*. Prepare a solution at a concentration of 5.0 milligrams per liter by dissolving 5.0 milligrams of chrysene in purified isooctane in a 1-liter volumetric flask. Adjust to volume with isooctane.

3. *Nitrogen gas*. Water pumped or equivalent purity, cylinder with regulator, and valve control flow at 5 p.s.i.

4. *Silica gel*. 100-200 mesh (Davison Chemical, Baltimore, Md., Grade 923, or equivalent), purified and activated by the following procedure: Place about 1 kilogram of silica gel in a large column and wash with contaminant-free benzene until a 200-milliliter sample of the benzene coming off the column will pass the ultraviolet absorption test for benzene. This test is performed as stipulated under "Organic solvents" in A under III above. When the silica gel has been sufficiently cleaned, activate the gel before use by placing the 1-kilogram batch in a shallow container in a layer no greater than 1 inch in depth and heating in an oven (Caution! Explosion Hazard) at 130 °C. for 16 hours, and store in a vacuum desiccator. Reheating about once a week is necessary if the silica gel is repeatedly removed from the desiccator.

5. *Aluminum oxide* (Aluminum Co. of America, Grade F-20, or equivalent grade), 80-200 mesh, purified and activated by the following procedure: Place about 1 kilogram of aluminum oxide in a large column and wash with contaminant-free benzene until a 200-milliliter sample of the benzene coming off the column will pass the ultraviolet absorption test for benzene. This test is performed as stipulated under "Organic solvents" in A under III above. (Caution! Remove Benzene From Adsorbent Under Vacuum To Minimize Explosion Hazard in Subsequent Heating!) When the aluminum oxide has been sufficiently cleaned and freed of solvent, activate it before use by placing the 1-kilogram batch in a shallow container in a layer no greater than 1 inch in depth. Heat in an oven at 130 °C for 16 hours. Upon removal from heat, store at atmospheric pressure over 80 percent (by weight) sulfuric acid in a desiccator for at least 36 hours before use. This gives aluminum oxide with between 6 to 9.5 percent volatiles. This is determined by heating a weighed sample of the prepared aluminum oxide at 2,000 °F for 2 hours and then quickly reweighing. To insure the proper adsorptive properties of the aluminum oxide, perform the following test:

a. Weigh 50 grams \pm 1 gram of the activated aluminum oxide and pack into the chromatographic column (1.3 centimeters \times 75 centimeters) described under "Apparatus" in C under I above. Use glass wool at the column exit to prevent the aluminum oxide from passing through the column.

b. Place a 250-milliliter graduated cylinder under the column to measure the amount of eluate coming from the column.

c. Prewet the aluminum oxide by passing 40 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off the column is between 1.5 to 2.5 milliliters per minute.

d. Just prior to the last of the isooctane reaching the top of the aluminum oxide bed,

add 10 milliliters of the isooctane solution containing 5.0 milligrams of chrysene per liter.

e. Continue percolation until the isooctane is just above the aluminum oxide. Then add 200 milliliters of a mixture of benzene and isooctane (33% percent benzene and 66% percent isooctane by volume) to the reservoir and continue percolation.

f. Continue percolation, collecting the eluates (40 milliliters of the prewet solution, 10 milliliters of the sample solution, and 200 milliliters of the gradient solution) in the 250-milliliter graduated cylinder until the level of the gradient solution is just above the aluminum oxide. Add 200 milliliters of the eluting solution of benzene and isooctane (90 percent benzene and 10 percent isooctane by volume) to the column and continue collecting until a total of 250 milliliters of solution has been obtained. This may be discarded. Now begin to collect the final eluate.

g. Place a 100-milliliter graduated cylinder under the column and continue the percolation until a 100-milliliter eluate has been obtained.

h. Measure the amount of chrysene in this 100-milliliter fraction by ultraviolet analysis. If the aluminum oxide is satisfactory, more than 80 percent of the original amount of chrysene should be found in this fraction. (NOTE: If the amount of chrysene recovered is less than 80 percent, the original batch of aluminum oxide should be sieved between 100-160 mesh. Activation and testing of this sieved batch should indicate a satisfactory aluminum oxide for use.)

IV. *Sampling*. Precautions must be taken to insure that an uncontaminated sample of the mineral oil is obtained since ultraviolet absorption is very sensitive to small amounts of extraneous material contaminating the sample through careless handling.

V. *Procedure*. A. *Blank*. Before proceeding with the analysis of a sample, determine the absorbance of the solvent residues by carrying out the procedure without a sample.

B. *Sample*. 1. Weigh out 20.0 grams \pm 0.1 gram of the mineral oil into a beaker and transfer to a 250-milliliter separatory funnel fitted with a tetrafluoroethylene polymer stopcock, using enough cyclohexane (25 milliliters) to give a final total volume of 50 milliliters (mineral oil plus cyclohexane).

2. Add 25 milliliters of nitromethane saturated with cyclohexane and shake by hand vigorously for 3 minutes. Recover the lower nitromethane layer in a 150-milliliter beaker containing 1 milliliter of *n*-hexadecane and evaporate on the steam bath under nitrogen. Repeat the extraction four more times, recovering each extract in the 150-milliliter beaker. Exercise care not to fill the beaker to such a capacity that solvent losses may occur. Evaporate the combined nitromethane extracts to 1 milliliter of *n*-hexadecane residue containing the

nitromethane-soluble mineral oil extractions. (NOTE: Complete removal of the nitromethane is essential. This can be assured by two successive additions of 5 milliliters of isooctane and reevaporation.)

3. Remove the beaker from the steam bath and allow to cool.

4. Weigh 50 grams \pm 1 gram of activated aluminum oxide and pack into the chromatographic column (1.3 centimeters \times 75 centimeters) described under "Apparatus" in C under I above. (NOTE: A small plug of glass wool is placed at the column exit to prevent the aluminum oxide from passing through the column. After adding aluminum oxide, tap the column lightly to remove air voids. All percolations using aluminum oxide are performed under nitrogen pressure. The 500-milliliter reservoir described under "Apparatus" in E under I above is to be used to hold the elution solvents.)

5. Prewet the column by adding 40 milliliters of isooctane to the column. Adjust nitrogen pressure so that rate of descent of the isooctane coming off the column is 2.0 to 3.0 milliliters per minute. Be careful to maintain the level of solvent in the reservoir to prevent air from entering the aluminum oxide bed. New or additional solvent is added just before the last portion of the previous solvent enters the bed. To minimize possible photo-oxidation effects, the following procedures (steps 6 through 18) shall be carried out in subdued light.

6. Before the last of the isooctane reaches the top of the aluminum oxide bed, release the nitrogen pressure and turn off the stopcock on the column. Transfer the *n*-hexadecane residue from the 150-milliliter beaker from procedure step 3 above onto the column, using several washes of isooctane (total volume of washes should be no greater than 10-15 milliliters).

7. Open the stopcock and continue percolation until the isooctane is about 1 centimeter above the top of the aluminum oxide bed. Add 200 milliliters of isooctane to the reservoir, and continue the percolation at the specified rate.

8. Just before the isooctane surface reaches the top of the aluminum oxide bed, add 200 milliliters of a mixture of benzene and isooctane (33% percent benzene and 66% percent isooctane by volume) to the reservoir, and continue the percolation.

9. Just before the surface of this mixture reaches the top of the aluminum oxide bed, release the nitrogen pressure, turn off the stopcock, and discard all the elution solvents collected up to this point.

10. Add to the reservoir 300 milliliters of a mixture of benzene and isooctane (90 percent benzene and 10 percent isooctane by volume), place a 25-milliliter graduated cylinder under the column, continue the percolation until 20 milliliters of eluate has been collected, and then discard the eluate.

11. At this point, place a clean 250-milliliter Erlenmeyer flask under the column. Continue the percolation and collect all the remaining eluate.

(NOTE: Allow the column to drain completely. An increase in the nitrogen pressure may be necessary as the last of the solvent comes off the column.)

12. Place 1 milliliter of *n*-hexadecane into a 150-milliliter beaker. Place this onto a steam bath under a nitrogen stream and transfer in small portions the eluate from step 11 above. Wash out the Erlenmeyer flask with small amounts of benzene and transfer to the evaporation beaker. Evaporate until only 1 milliliter of hexadecane residue remains. (NOTE: Complete removal of the benzene is essential. This can be assured by two successive additions of 5 milliliters of isooctane and reevaporation.)

13. Remove the beaker from the steam bath and cool.

14. Place a sample of 113.5 grams activated 100-200-mesh silica gel in a 500-milliliter glass-stoppered Erlenmeyer flask. Add to the silica gel 46.2 grams (41 milliliters) of nitromethane. Stopper and shake the flask vigorously until no lumps of silica gel are observed and then shake occasionally during a period of 1 hour. The resultant nitromethane-treated silica gel is 29 weight-percent nitro-methane and 71 weight-percent silica gel.

15. Place a small plug of glass wool in the tapered end of the 1.7 centimeters outside diameter \times 115 centimeters column, described under "Apparatus" in D of I above, adjacent to the stopcock to prevent silica gel from passing through the stopcock. Pack the nitromethane-treated silica gel into the column, tapping lightly. The resultant silica gel bed should be about 95 centimeters in depth. Place into a flask 170 milliliters of isooctane saturated with nitromethane.

16. Place a 100-milliliter graduated cylinder under the column and transfer the residue from the beaker in procedure step 13 above with several washes of the 170 milliliters of isooctane, saturated with nitromethane, onto the top of the column. (Total volume of washes should be no greater than 10 to 15 milliliters.) Permit isooctane solution to enter the silica gel bed until the liquid level is at the top bed level. Place the remaining amount of the 170 milliliters of isooctane, saturated with nitromethane, in the reservoir above the bed for percolation through the silica gel. Apply nitrogen pressure to the top of the column, adjusting the pressure so that the isooctane is collected at the rate of 2.5 to 3.5 milliliters per minute, and percolate isooctane through the bed until a quantity of 75.0 milliliters of eluate is collected. Discard the 75 milliliters of eluate. Turn off the stopcock and add 250 milliliters of benzene to the reservoir above the bed.

Use a 400-milliliter beaker to collect the remaining eluate.

17. Open the stopcock, renew the pressure, and percolate the remaining isooctane and benzene through the column eluting the remaining aromatics. Transfer the eluate in small portions from the 400 milliliter beaker to a 150-milliliter beaker containing 1 milliliter of *n*-hexadecane and evaporate on the steam bath under nitrogen. Rinse the 400-milliliter beaker well with small portions of isooctane to obtain a complete transfer.

(NOTE: Complete removal of the nitromethane and benzene is essential. This can be assured by successive additions of 5 milliliters of isooctane and reevaporation.)

18. Transfer the residue with several washes of isooctane into a 200-milliliter volumetric flask. Add isooctane to mark.

19. Record the spectrum of the sample solution in a 1-centimeter cell compared to isooctane from 270 to 400 mμ. After making necessary corrections in the spectrum for cell differences and for the blank absorbance, record the maximum absorbance in each of the wavelength intervals (mμ), 280-299, 300-319, 320-359, 360-400.

a. If the spectrum then shows no discernible peak corresponding to the absorbance maximum of the pyrene reference standard solution at 334 mμ, the maximum absorbances in the respective wavelength intervals recorded shall not exceed those prescribed in paragraph (d)(1)(ii) of this section.

b. If such a peak is evident in the spectrum of the sample solution, and the spectrum as a whole is not incompatible with that of a pyrene contaminant yielding such a peak of the observed absorbance, calculate the concentration of pyrene that would yield this peak (334 m) by the base-line technique described in ASTM method E169-63 (Reapproved 1981), "Standard Recommended Practices for General Techniques of Ultraviolet Quantitative Analysis," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section. Correct each of the maximum absorbances in the respective specified wavelength intervals by subtracting the absorbance due to pyrene, determined as follows:

$$\text{Absorbance due to pyrene} = \frac{C_p \times S_a}{S_p}$$

where:

C_p=Calculated concentration of pyrene in sample solution;

S_p=Concentration of pyrene reference standard solution in same units of concentration;

S_a=Absorbance of pyrene reference standard solution at wavelength of maximum absorbance of sample solution in the respective specified wavelength intervals.

Also calculate the pyrene content of the oil sample in parts per million as follows:

$$\text{Pyrene content (p.p.m.)} = \frac{(200/1000) \times C}{20/1000} = 10C$$

where:

C=Calculated concentration of pyrene in milligrams per liter of sample solution.

c. The pyrene content so determined shall not exceed 25 p.p.m. The maximum absorbances corrected for pyrene content as described in this step 19 for each of the specified wavelength intervals shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

d. If the spectrum as a whole of the sample solution is in any respect clearly incompatible with the presence of pyrene as the source of the peak at 334 mμ, then the maximum absorbances in the respective wavelength intervals without correction for any assumed pyrene content shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 49 FR 10112, Mar. 19, 1984; 54 FR 24898, June 12, 1989]

§ 178.3650 Odorless light petroleum hydrocarbons.

Odorless light petroleum hydrocarbons may be safely used, as a component of nonfood articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The additive is a mixture of liquid hydrocarbons derived from petroleum or synthesized from petroleum gases. The additive is chiefly paraffinic, isoparaffinic, or naphthenic in nature.

(b) The additive meets the following specifications:

- (1) Odor is faint and not kerosenic.
- (2) Initial boiling point is 300 °F minimum.
- (3) Final boiling point is 650 °F maximum.

(4) Ultraviolet absorbance limits determined by method specified in § 178.3620(b)(1)(ii), as follows:

Wavelength (Mμ)	Maximum absorbance per centimeter optical pathlength
280 to 299	4.5
290 to 299	3.5
300 to 329	2.5

basic resins produced by the polymerization of vinyl fluoride.

(b) The poly(vinyl fluoride) basic resins have an intrinsic viscosity of not less than 0.75 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(1) *Solvent.* *N,N*-Dimethylacetamide, technical grade.

(2) *Solution.* Powdered resin and solvent are heated at 120 °C until the resin is dissolved.

(3) *Temperature.* Flow times of the solvent and solution are determined at 110 °C.

(4) *Viscometer.* Cannon-Ubbelohde size 50 semimicro dilution viscometer (or equivalent).

(5) *Calculation.* The calculation method used is that described in appendix X 1.3 (ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference; see paragraph (b) of this section for availability of the incorporation by reference) with the reduced viscosity determined for three concentration levels not greater than 0.5 gram per deciliter and extrapolated to zero concentration for intrinsic viscosity. The following formula is used for determining reduced viscosity:

$$\text{Reduced viscosity in terms of deciliters per gram} = \frac{t - t_0}{t_0 \times c}$$

where:

t=Solution efflux time.

*t*₀=Solvent efflux time.

c=Concentration of solution in terms of grams per deciliter.

[42 FR 14534, Mar. 15, 1977, as amended at 47 FR 11839, Mar. 19, 1982; 49 FR 10107, Mar. 19, 1984]

§ 175.300 Resinous and polymeric coatings.

Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in

producing, manufacturing, packaging, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film or enamel over a metal substrate, or the coating is intended for repeated food-contact use and is applied to any suitable substrate as a continuous film or enamel that serves as a functional barrier between food and the substrate. The coating is characterized by one or more of the following descriptions:

(1) Coatings cured by oxidation.

(2) Coatings cured by polymerization, condensation, and/or cross-linking without oxidation.

(3) Coatings prepared from prepolymers.

(b) The coatings are formulated from optional substances that may include:

(1) Substances generally recognized as safe in food.

(2) Substances the use of which is permitted by regulations in this part or which are permitted by prior sanction or approval and employed under the specific conditions, if any, of the prior sanction or approval.

(3) Any substance employed in the production of resinous and polymeric coatings that is the subject of a regulation in subchapter B of this chapter and conforms with any specification in such regulation. Substances named in this paragraph (b)(3) and further identified as required:

(i) Drying oils, including the triglycerides or fatty acids derived therefrom:

Beechnut.
Candlenut.
Castor (including dehydrated).
Chinawood (tung).
Coconut.
Corn.
Cottonseed.
Fish (refined).
Hempseed.
Linseed.
Oiticica.
Perilla.
Poppyseed.
Pumpkinseed.
Safflower.
Sesame.
Soybean.
Sunflower.
Tall oil.

**5076**

5076 is a 100 percent active liquid release agent. It is designed for application to food processing equipment to prevent sticking and buildup.

RECOMMENDED USAGE LEVELS

5 ppm maximum, based on the total weight of food contacting the release agent between applications.

FDA COMPLIANCE

5076 is a combination of FDA GRAS and direct approved substances. Further information is available on request.

TYPICAL PROPERTIES

Appearance	White, opaque liquid
Specific Gravity @ 77°F	0.904
Weight per Gallon	7.53
Pour point, °F	15

5076 contains components listed on the TSCA inventory, and they are listed on the DSL, or otherwise comply with CEPA New Substance Notification.

STORAGE AND HANDLING

If stored outside, product should be brought to room temperature prior to using. Product may show slight separation on extended storage and should be stirred prior to use.

SHIPPING

Shipped in 55 gallon non-returnable drums or 5 gallon pails.

000033

Bulletin TD654-L
(Rev. 2/15/00)

Pages 000034 - 000039 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Pages 000040 - 000041 removed under the Privacy Act of 1974.

silent on potential retroactive application of the rule, retroactive application violates the APA's notice and comment procedures.⁶

Discussion

We will deny PG&E's request for clarification, reconsideration and rehearing.

We disagree with PG&E that the Commission must clarify or reconsider the Final Rule at this time because of retroactivity concerns. In the Final Rule, the Commission did not state that it necessarily would take any particular action. Rather, the Commission merely stated that challenges to affiliate fuel prices recovered through the fuel adjustment clause prior to the effective date of this rule change are best decided on a case-by-case basis. When the Commission is presented with a case involving fuel adjustment clause recovery before the effective date of the Final Rule of the price of affiliate fuel purchases, the Commission can determine at that time how best to proceed.

The Commission Orders

PG&E's request for clarification, reconsideration and rehearing is hereby denied, as discussed in the body of this order.

By the Commission.

(SEAL)

David P. Boergers,
Secretary.

[FR Doc. 98-31960 Filed 11-30-98; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 94F-0454]

Food Additives Permitted for Direct Addition to Food for Human Consumption; White Mineral Oil, USP

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of white mineral oil as a dust control agent for rough rice at an application rate of 800 parts per million (ppm). This action is in response to a petition filed by Lyondell-Citgo Refining Co., Ltd.

DATES: This regulation is effective December 1, 1998; written objections and requests for a hearing by December 31, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3106.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the *Federal Register* of January 25, 1995 (60 FR 4920), FDA announced that a food additive petition (FAP 5A4440) had been filed by Lyondell-Citgo Refining Co., Ltd., P.O. Box 2451, Houston, TX 77252-2451, proposing that the food additive regulations be amended in § 172.878 *White mineral oil* (21 CFR 172.878), to provide for the safe use of white mineral oil as a dust control agent for rough rice at an application rate of 800 ppm (0.08 percent of the weight of the rice). An application rate of 200 ppm (0.02 percent of the weight of the grain) is currently permitted under § 172.878(c) for use on wheat, corn, soybean, barley, rice, rye, oats, and sorghum as a dust suppressant. On September 17, 1996, the petitioner amended the petition to limit its request to the use of white mineral oil of ISO 100 oil viscosity (100 centistokes (cSt) at 100°F).

II. Comments

The agency has received nine comments from rice warehouses and an oil supply company in support of the proposed application rate of food grade white mineral oil for rough rice indicating that the current regulated rate of 200 ppm does not effectively control rice dust. Because the comments are consistent with the regulation as set forth in the codified section of this document, FDA sees no need to address them.

III. Conclusion

The agency has evaluated all the data in the petition and other information and concludes that the proposed use of white mineral oil of ISO 100 oil viscosity (centistokes (cSt) at 100 °F) is safe for use as a dust control agent for rough rice and that the additive will achieve its technical effect. Therefore, the agency concludes that the food additive regulations should be amended as set forth as follows.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Effects

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before December 31, 1998, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in

⁶ 5 U.S.C. 553 (1994).

2875

000042

response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to

the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.878 is amended in the table in paragraph (c) by adding an entry under the headings "Use" and "Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)" to read as follows:

§ 172.878 White mineral oil.

* * * * *

(c) * * *

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)
16. As a dust control agent for rice.	ISO 100 oil viscosity (100 centistokes (cSt) at 100°F) applied at a level of no more than 0.08 percent by weight of the rice grain.

Dated: November 7, 1998.

L. Robert Lake,

Director, Office of Policy, Planning, and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 98-31845 Filed 11-30-98; 8:45 am]

BILLING CODE 4180-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 98F-0063]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Natamycin (Pimaricin)

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a dry form of natamycin as an antimycotic in cheeses. This action is in response to a petition filed by Protein Technologies International, Inc.

DATES: This regulation is effective December 1, 1998; written objections and requests for a hearing by December 31, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

JoAnn Ziyad, Center for Food Safety and Applied Nutrition (HFS-206), Food and

Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3116.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of February 11, 1998 (63 FR 6945), FDA announced that a food additive petition (FAP 8A4581) had been filed by Protein Technologies International, Checkerboard Sq., St. Louis, MO 63164. The petition proposes to amend the food additive regulations in § 172.155 *Natamycin (pimaricin)* (21 CFR 172.155) to provide for the safe use of a dry form of the food additive for use on the surfaces of cuts and slices of cheese to inhibit mold spoilage, in accordance with various standards of identity for cheeses that allow the use of antimycotics and anticaking agents.

FDA received two comments from the food industry on the use of the dry mix of natamycin and cellulose on cheese to inhibit mold spoilage. Both comments favored the petitioned use of the additive. One comment listed several reasons for supporting the current petitioned use. They include possible extension of shelf life of shredded cheese, reduction of risks associated with antimycotic suspension spray application and minimal new technology investment by utilizing existing anticaking agent application technology. However, the other comment stated that "We realize that natamycin is permitted as a spray on the surface of cheese, but we are not comfortable with that method of application on grated cheese. We would like to test the efficacy of the method proposed in the cited petition."

FDA finds that the petitioner does not seek approval either for the use of the wet or dry application of the additive on

grated cheese. The petitioner requests that FDA amend the food additive regulation for natamycin (pimaricin) found in § 172.155 to allow for the use of a dry form of the food additive only on the surfaces of cuts and slices of cheese to inhibit mold spoilage, and this does not extend to use of the additive on grated or shredded cheese. Therefore, the comments on grated or shredded cheese are outside the scope of this rulemaking.

Natamycin is currently approved in § 172.155 for use as an antimycotic agent on the surfaces of cuts and slices of cheese(s). Natamycin may be used on surfaces of cuts and slices of a cheese listed in 21 CFR part 133 only if the standards for such cheese provides for or the use of "safe and suitable" mold-inhibiting ingredients. The subject additive is defined in § 172.155 and may be applied by dipping or by spraying, using an aqueous solution containing 200 to 300 parts per million (ppm) of the additive. The proposed use is for the application of natamycin to cuts and slices of cheese as a dry mixture with safe and suitable anticaking agents, such as cellulose.

FDA has evaluated the data in the petition and other relevant material. As part of its review, FDA evaluated data on the technical effect of the additive, its stability, and the change in exposure resulting from the use of a dry mixture of natamycin and cellulose anticaking agent. The petitioner provided data to establish that a level of up to 20 ppm natamycin in the finished product is needed to obtain the same antimycotic effect as from the liquid application.

The petitioner, by measuring the antimycotic effect of a dry mixture of natamycin and cellulose on several

000043

21 CFR Ch. I (4-1-98 Edition)

Food and Drug Administration, HHS

§ 172.878

70 Hydroxypropyl cellulose.

food additive hydroxypropyl cellulose may be safely used in food, except in standardized foods that do not require such use, in accordance with the following prescribed conditions:

The additive consists of one of the following:

(1) A cellulose ether containing propylene glycol groups attached by an ether linkage which contains, on an anhydrous basis, not more than 4.6 hydroxypropyl groups per anhydroglucose unit. The additive has a minimum viscosity of 145 centipoises at 25 °C.

(2) A cellulose ether containing propylene glycol groups attached by an ether linkage having a hydroxypropoxy ($\text{H}_3\text{COCH}_2\text{CH}_2\text{OH}$) content of 5 to 16 percent by weight (w/w) on an anhydrous basis, i.e., 0.1 to 0.4 hydroxypropyl groups per anhydroglucose unit. The common name for this form of the additive is low substituted hydroxypropyl cellulose.

(3) The additive is used or intended for use as follows:

(a) The additive identified in paragraph (a)(1) of this section is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

(b) The additive identified in paragraph (a)(2) of this section is used or intended for use as a binder and disintegrator in tablets or wafers containing dietary supplements of vitamins and/or minerals. The additive is used in accordance with good manufacturing practice.

FR 50065, Oct. 9, 1981]

72.872 Methyl ethyl cellulose.

The food additive methyl ethyl cellulose may be safely used in food in accordance with the following prescribed conditions.

(a) The additive is a cellulose ether having the general formula $[\text{C}_6\text{H}_7\text{O}_5(\text{CH}_3)_x(\text{C}_2\text{H}_5)_y]_n$, where x is the number of methyl groups and y is the number of ethyl groups. The average value

of x is 0.3 and the average value of y is 0.7.

(b) The additive meets the following specifications:

(1) The methoxy content shall be not less than 3.5 percent and not more than 6.5 percent, calculated as OCH_3 , and the ethoxy content shall be not less than 14.5 percent and not more than 19 percent, calculated as OC_2H_5 , both measured on the dry sample.

(2) The viscosity of an aqueous solution, 2.5 grams of the material in 100 milliliters of water, at 20 °C, is 20 to 60 centipoises.

(3) The ash content on a dry basis has a maximum of 0.6 percent.

(c) The food additive is used as an aerating, emulsifying, and foaming agent, in an amount not in excess of that reasonably required to produce its intended effect.

§ 172.874 Hydroxypropyl methylcellulose.

The food additive hydroxypropyl methylcellulose (CAS Reg. No. 9004-65-3) may be safely used in food, except in standardized foods which do not provide for such use if:

(a) The additive complies with the definition and specifications prescribed in the National Formulary, 12th edition.

(b) It is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

(c) To insure safe use of the additive, the container of the additive, in addition to being labeled as required by the general provisions of the act, shall be accompanied by labeling which contains adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 38273, Aug. 31, 1982]

§ 172.876 Castor oil.

The food additive castor oil may be safely used in accordance with the following conditions:

(a) The additive meets the specifications of the United States Pharmacopeia XX (1980).

(b) The additive is used or intended for use as follows:

Use and Limitations

Hard candy production—As a release agent and antisticking agent, not to exceed 500 parts per million in hard candy.

Vitamin and mineral tablets—As a component of protective coatings.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.878 White mineral oil.

White mineral oil may be safely used in food in accordance with the following conditions:

(a) White mineral oil is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum. It is refined to meet the following specifications:

(1) It meets the test requirements of the United States Pharmacopeia XX (1980) for readily carbonizable substances (page 532).

(2) It meets the test requirements of U.S.P. XVII for sulfur compounds (page 400).

(3) It meets the specifications prescribed in the "Journal of the Association of Official Analytical Chemists," Volume 45, page 66 (1962), which is incorporated by reference, after correction of the ultraviolet absorbance for any absorbance due to added antioxidants. Copies of the material incorporated by reference are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(b) White mineral oil may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

(c) White mineral oil is used or intended for use as follows:

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)
1. As a release agent, binder, and lubricant in or on capsules and tablets containing concentrates of flavoring, spices, condiments, and nutrients intended for addition to food, excluding confectionery.	Not to exceed 0.6% of the capsule or tablet.
2. As a release agent, binder, and lubricant in or on capsules and tablets containing food for special dietary use.	Not to exceed 0.6% of the capsule or tablet.
3. As a float on fermentation fluids in the manufacture of vinegar and wine to prevent or retard access of air, evaporation, and wild yeast contamination during fermentation.	In an amount not to exceed good manufacturing practice.
4. As a defoamer in food	In accordance with § 173.340 of this chapter.
5. In bakery products, as a release agent and lubricant	Not to exceed 0.15% of bakery products.
6. In dehydrated fruits and vegetables, as a release agent	Not to exceed 0.02% of dehydrated fruits and vegetables.
7. In egg white solids, as a release agent	Not to exceed 0.1% of egg white solids.
8. On raw fruits and vegetables, as a protective coating	In an amount not to exceed good manufacturing practice.
9. In frozen meat, as a component of hot-melt coating	Not to exceed 0.095% of meat.
10. As a protective float on brine used in the curing of pickles	In an amount not to exceed good manufacturing practice.
11. In molding starch used in the manufacture of confectionery	Not to exceed 0.3 percent in the molding starch.
12. As a release agent, binder, and lubricant in the manufacture of yeast	Not to exceed 0.15 percent of yeast.
13. As an antidusting agent in sorbic acid for food use	Not to exceed 0.25 percent in the sorbic acid.
14. As release agent and as sealing and polishing agent in the manufacture of confectionery.	Not to exceed 0.2 percent of confectionery.
15. As a dust control agent for wheat, corn, soybean, barley, rice, rye, oats, and sorghum.	Applied at a level of no more than 0.02 percent by weight of grain.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 8764, Mar. 2, 1982; 47 FR 11838, Mar. 19, 1982; 48 FR 55728, Dec. 15, 1983; 49 FR 10105, Mar. 19, 1984; 54 FR 24897, June 12, 1989]

§ 172.880 Petrolatum.

Petrolatum may be safely used in food, subject to the provisions of this section.

(a) Petrolatum complies with the specifications set forth in the United States Pharmacopeia XX (1980) for white petrolatum or in the National Formulary XV (1980) for petrolatum.

(b) Petrolatum meets the following ultraviolet absorbance limits when

subjected to the analytical procedure described in § 172.886(b):

Ultraviolet absorbance per centimeter path length:

Millimicrons	Maximum
280-289	0.25
290-29920
300-35914
360-40004

(c) Petrolatum is used or intended for use as follows:

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with petrolatum)
In bakery products; as release agent and lubricant	With white mineral oil, not to exceed 0.15 percent of bakery product.
In confectionery; as release agent and as sealing and polishing agent	Not to exceed 0.2 percent of confectionery.
In dehydrated fruits and vegetables; as release agent	Not to exceed 0.02 percent of dehydrated fruits and vegetables.
In egg white solids; as release agent	Not to exceed 0.1 percent of egg white solids.
On raw fruits and vegetables; as protective coating	In an amount not to exceed good manufacturing practice.
In beet sugar and yeast; as defoaming agent	As prescribed in § 173.340 of this chapter.

red meat as a component of a carcass spray in accordance with current industry practice. In the carcass spray, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm) in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9.

(d) The concentration of sodium chlorite is determined by a method entitled "Determination of Sodium Chlorite: 50 ppm to 1500 ppm Concentration," September 13, 1995, developed by Alcide Corp., Redmond, WA, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, or

may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC 20204-0001, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

[61 FR 17829, Apr. 23, 1996, as amended at 63 FR 11119, Mar. 6, 1998]

§ 173.340 Defoaming agents.

Defoaming agents may be safely used in processing foods, in accordance with the following conditions:

(a) They consist of one or more of the following:

(1) Substances generally recognized by qualified experts as safe in food or covered by prior sanctions for the use prescribed by this section.

(2) Substances listed in this paragraph (a)(2) of this section, subject to any limitations imposed:

Substances	Limitations
Dimethylpolysiloxane (substantially free from hydrolyzable chloride and alkoxy groups; no more than 18 percent loss in weight after heating 4 hours at 200 °C; viscosity 300 to 1,050 centistokes at 25 °C; refractive index 1.400-1.404 at 25 °C).	10 parts per million in food, or at such level in a concentrated food that when prepared as directed on the labels, the food in its ready-for-consumption state will have not more than 10 parts per million except as follows: Zero in milk; 110 parts per million in dry gelatin dessert mixes labeled for use whereby no more than 16 parts per million is present in the ready-to-serve dessert; 250 parts per million in salt labeled for cooking purposes, whereby no more than 10 parts per million is present in the cooked food.
Formaldehyde	As a preservative in defoaming agents containing dimethylpolysiloxane, in an amount not exceeding 1.0 percent of the dimethylpolysiloxane content.
α-Hydro-omega-hydroxy-poly (oxyethylene)/poly(oxypropylene) (minimum 15 moles/poly(oxyethylene) block copolymer (CAS Reg. No. 9003-11-6) as defined in § 172.808(a)(3) of this chapter.	For use as prescribed in § 172.808(b)(3) of this chapter.
Polyacrylic acid, sodium salt	As a stabilizer and thickener in defoaming agents containing dimethylpolysiloxane in an amount reasonably required to accomplish the intended effect.
Polyethylene glycol	As defined in § 172.820 of this chapter.
Polyoxyethylene 40 monostearate	As defined in U.S.P. XVI.
Polysorbate 60	As defined in § 172.836 of this chapter.
Polysorbate 65	As defined in § 172.838 of this chapter.
Propylene glycol alginate	As defined in § 172.858 of this chapter.
Silicon dioxide	As defined in § 172.480 of this chapter.
Sorbitan monostearate	As defined in § 172.842 of this chapter.
White mineral oil: Conforming with § 172.878 of this chapter	As a component of defoaming agents for use in wash water for sliced potatoes at a level not to exceed 0.008 percent of the wash water.

(3) Substances listed in this paragraph (a)(3), provided they are components of defoaming agents limited to use in processing beet sugar and yeast, and subject to any limitations imposed:

Substances	Limitations
Aluminum stearate	As defined in § 172.863 of this chapter.
Butyl stearate	
BHA	As an antioxidant, not to exceed 0.1 percent by weight of defoamer.
BHT	Do.
Calcium stearate	As defined in § 172.863 of this chapter.
Fatty acids	As defined in § 172.860 of this chapter.

Substances	Limitations
Formaldehyde	As a preservative.
Hydroxylated lecithin	As defined in § 172.814 of this chapter.
Isopropyl alcohol	
Magnesium stearate	As defined in § 172.863 of this chapter.
Mineral oil: Conforming with § 172.878 of this chapter	Not more than 150 p.p.m. in yeast, measured as hydrocarbons.
Odorless light petroleum hydrocarbons: Conforming with § 172.884 of this chapter.	
Petrolatum: Conforming with § 172.880 of this chapter	
Petroleum wax: Conforming with § 172.886 of this chapter.	
Petroleum wax, synthetic.	
Polyethylene glycol (400)dioleate: Conforming with § 172.820(a)(2) of this chapter and providing the oleic acid used in the production of this substance complies with § 172.860 or § 172.862 of this chapter.	As an emulsifier not to exceed 10 percent by weight of defoamer formulation.
Synthetic isoparaffinic petroleum hydrocarbons: Conforming with § 172.882 of this chapter.	
Oleic acid derived from tall oil fatty acids	Complying with § 172.862 of this chapter.
Oxystearin	As defined in § 172.818 of this chapter.
Polyoxyethylene (600) dioleate.	
Polyoxyethylene (600) mononoleate.	
Polypropylene glycol	Molecular weight range, 1,200-3,000.
Polysorbate 80	As defined in § 172.840 of this chapter.
Potassium stearate	As defined in § 172.863 of this chapter.
Propylene glycol mono- and diesters of fats and fatty acids	As defined in § 172.856 of this chapter.
Soybean oil fatty acids, hydroxylated.	
Tallow, hydrogenated, oxidized or sulfated.	
Tallow alcohol, hydrogenated.	

(4) The substance listed in this paragraph (a)(4), provided it is a component of defoaming agents limited to use in processing beet sugar only, and subject to the limitations imposed:

Substance	Limitations
<i>n</i> -Butoxypoly(oxyethylene)-poly(oxypropylene)glycol.	Viscosity range, 4,850-5,350 Saybolt Universal Seconds (SUS) at 37.8 °C (100 °F). The viscosity range is determined by the method "Viscosity Determination of <i>n</i> -butoxypoly(oxyethylene)-poly(oxypropylene) glycol" dated April 26, 1995, developed by Union Carbide Corp., P.O. Box 670, Bound Brook, NJ 08805, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the material incorporated by reference are available from the Division of Pesticide Control, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, and may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

§ 175.210

Tri(mixed mono- and dinonylphenyl) phosphite (which may contain not more than 1 percent by weight of triisopropanolamine).

(c) Acrylonitrile copolymers identified in this section shall comply with the provisions of §180.22 of this chapter.

[42 FR 14534, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977; 48 FR 15617, Apr. 12, 1983; 63 FR 3464, Jan. 23, 1998]

Subpart C—Substances for Use as Components of Coatings

§ 175.210 Acrylate ester copolymer coating.

Acrylate ester copolymer coating may safely be used as a food-contact surface of articles intended for packaging and holding food, including heating of prepared food, subject to the provisions of this section:

(a) The acrylate ester copolymer is a fully polymerized copolymer of ethyl acrylate, methyl methacrylate, and methacrylic acid applied in emulsion form to molded virgin fiber and heat-cured to an insoluble resin.

(b) Optional substances used in the preparation of the polymer and in the preparation and application of the emulsion may include substances named in this paragraph, in an amount not to exceed that required to accomplish the desired technical effect and subject to any limitation prescribed: *Provided, however,* That any substance named in this paragraph and covered by a specific regulation in subchapter B of this chapter must meet any specifications in such regulation.

List of substances	Limitations
Aluminum stearate. Ammonium lauryl sulfate. Borax	Not to exceed the amount required as a preservative in emulsion defoamer. Do.
Disodium hydrogen phosphate Formaldehyde. Glyceryl monostearate. Methyl cellulose. Mineral oil. Paraffin wax. Potassium hydroxide. Potassium persulfate. Tallow. Tetrasodium pyrophosphate. Titanium dioxide.	

21 CFR Ch. I (4-1-98 Edition)

(c) The coating in the form in which it contacts food meets the following tests:

(1) An appropriate sample when exposed to distilled water at 212 °F for 30 minutes shall yield total chloroform-soluble extractables not to exceed 0.5 milligram per square inch.

(2) An appropriate sample when exposed to *n*-heptane at 120 °F for 30 minutes shall yield total chloroform-soluble extractables not to exceed 0.5 milligram per square inch.

§ 175.230 Hot-melt strippable food coatings.

Hot-melt strippable food coatings may be safely applied to food, subject to the provisions of this section.

(a) The coatings are applied to and used as removable coatings for food.

(b) The coatings may be prepared, as mixtures, from the following substances:

(1) Substances generally recognized as safe in food.

(2) Substances identified in this subparagraph.

List of substances	Limitations
Acetylated monoglycerides	Complying with 172.828 of this chapter.
Cellulose acetate butyrate. Cellulose acetate propionate. Mineral oil, white	
	For use only as a component of hot-melt strippable food coatings applied to frozen meats and complying with § 172.878 of this chapter.

§ 175.250 Paraffin (synthetic).

Synthetic paraffin may be safely used as an impregnant in, coating on, or component of coatings on articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) The additive is synthesized by the Fischer-Tropsch process from carbon monoxide and hydrogen, which are catalytically converted to a mixture of paraffin hydrocarbons. Lower molecular-weight fractions are removed by distillation. The residue is hydrogenated and may be further treated by percolation through activated charcoal. This mixture can be fractionated

§ 178.3530 Isoparaffinic petroleum hydrocarbons, synthetic.

Isoparaffinic petroleum hydrocarbons, synthetic, may be safely used in the production of nonfood articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The isoparaffinic petroleum hydrocarbons, produced by synthesis from petroleum gases consist of a mixture of liquid hydrocarbons meeting the following specifications:

Boiling point 63° -260 °C, as determined by ASTM method D86-82, "Standard Method for Distillation of Petroleum Products," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

Ultraviolet absorbance:

260-319 millimicrons—1.5 maximum.

320-329 millimicrons—0.08 maximum.

330-350 millimicrons—0.05 maximum.

Nonvolatile residue 0.002 gram per 100 milliliters maximum.

Synthetic isoparaffinic petroleum hydrocarbons containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application to mineral oil under "Specifications" on page 66 of the "Journal of the Association of Official Agricultural Chemists," Vol. 45 (February 1962), which is incorporated by reference, disregarding the last sentence of that procedure. For hydrocarbons boiling below 121 °C, the nonvolatile residue shall be determined by ASTM method D1353-78, "Standard Test Method for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products;" for those boiling above 121 °C, ASTM procedure D381-80, "Standard Test

Method for Existent Gum in Fuels by Jet Evaporation," which are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(b) Isoparaffinic petroleum hydrocarbons may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended technical effect.

(c) Isoparaffinic petroleum hydrocarbons are used in the production of nonfood articles. The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect, and the residual remaining in the finished article shall be the minimum amount reasonably attainable.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 49 FR 10112, Mar. 19, 1984]

§ 178.3570 Lubricants with incidental food contact.

Lubricants with incidental food contact may be safely used on machinery used for producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The lubricants are prepared from one or more of the following substances:

(1) Substances generally recognized as safe for use in food.

(2) Substances used in accordance with the provisions of a prior sanction or approval.

(3) Substances identified in this paragraph (a)(3).

Substances	Limitations
Aluminum stearoyl benzoyl hydroxide	For use only as a thickening agent in mineral oil lubricants at a level not to exceed 10 pct by weight of the mineral oil.
N,N-Bis(2-ethylhexyl)-az-methyl-1H-benzotriazole-1-methanamine (CAS Reg. No. 94270-86-7).. BHA. BHT.	For use as a copper deactivator at a level not to exceed 0.1 percent by weight of the lubricant.
α-Butyl-omega-hydroxypoly(oxyethylene) poly(oxypropylene) produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9038-95-3.	Addition to food not to exceed 10 parts per million.

Substances	Limitations
α -Butyl- ω -hydroxypoly(oxypropylene); minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-13-8.	Do.
Castor oil	Do.
Castor oil, dehydrated	Do.
Castor oil, partially dehydrated	Do.
Dialkyldimethylammonium aluminum silicate (CAS Reg. No. 68953-58-2), which may contain up to 7 percent by weight 1,6-hexanediol (CAS Reg. No. 629-11-6), where the alkyl groups are derived from hydrogenated tallow fatty acids (C_{14} - C_{18}) and where the aluminum silicate is derived from bentonite.	For use only as a gelling agent in mineral oil lubricants at a level not to exceed 15 percent by weight of the mineral oil.
Dimethylpolysiloxane (viscosity greater than 300 centistokes) ...	Addition to food not to exceed 1 part per million.
Disodium decanedioate (CAS Reg. No. 17265-14-4)	For use only: 1. As a corrosion inhibitor or rust preventative in mineral oil-bentonite lubricants at a level not to exceed 2 percent by weight of the grease. 2. As a corrosion inhibitor or rust preventative only in greases at a level not to exceed 2 percent by weight of the grease.
Disodium EDTA (CAS Reg. No. 139-33-3)	For use only as a chelating agent and sequestrant at a level not to exceed 0.06 percent by weight of lubricant at final use dilution.
Ethoxylated resin phosphate ester mixture consisting of the following compounds:	For use only as a surfactant to improve lubricity in lubricating fluids complying with this section at a level not to exceed 5 percent by weight of the lubricating fluid.
1. Poly(methylene- <i>p</i> - <i>tert</i> -butyl- phenoxy)poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters (0 to 40 percent of the mixture). The resin is formed by condensation of 1 mole of <i>p</i> - <i>tert</i> -butyl-phenol with 2 to 4 moles of formaldehyde and subsequent ethoxylation with 4 to 12 moles of ethylene oxide.	
2. Poly(methylene- <i>p</i> -nonylphenoxy) poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters (0 to 40 percent of the mixture). The resin is formed by condensation of 1 mole of <i>p</i> -nonylphenol with 2 to 4 moles of formaldehyde and subsequent ethoxylation with 4 to 12 moles of ethylene oxide; and.	
3. <i>n</i> -Tidecyl alcohol mixture of dihydrogen phosphate and monohydrogen phosphate esters (40 to 80 percent of the mixture; CAS Reg. No. 56831-62-0).	
Fatty acids derived from animal or vegetable sources, and the hydrogenated forms of such fatty acids.	
2-(8-Heptadecenyl)-4,5-dihydro-1 <i>H</i> -imidazole-1-ethanol (CAS Reg. No. 95-38-5).	For use at levels not to exceed 0.5 percent by weight of the lubricant.
Hexamethylenes(3,5-di- <i>tert</i> -butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 35074-77-2).	For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
α -Hydro- ω -hydroxypoly (oxyethylene) poly(oxypropylene) produced by random condensation of mixtures of ethylene oxide and propylene oxide containing 25 to 75 percent by weight of ethylene oxide; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-11-6.	Addition to food not to exceed 10 parts per million.
12-Hydroxystearic acid.	
Isopropyl oleate	For use only as an adjuvant (to improve lubricity) in mineral oil lubricants.
Magnesium ricinoleate	For use only as an adjuvant in mineral oil lubricants at a level not to exceed 10 percent by weight of the mineral oil.
Mineral oil	Addition to food not to exceed 10 parts per million.
<i>N</i> -Methyl- <i>N</i> -(1-oxo-9-octadecenyl)glycine (CAS Reg. No. 110-25-8).	For use as a corrosion inhibitor at levels not to exceed 0.5 percent by weight of the lubricant.
<i>N</i> -phenylbenzenamine, reaction products with 2,4,4-trimethylpentene (CAS Reg. No. 68411-46-1).	For use only as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
Petrolatum	Complying with § 178.3700. Addition to food not to exceed 10 parts per million.
Phenyl- α -and/or phenyl- β -naphthylamine	For use only, singly or in combination, as antioxidant in mineral oil lubricants at a level not to exceed a total of 1 percent by weight of the mineral oil.
Phosphoric acid, mono- and dihexyl esters, compounds with tetramethylenediamines and C_{12-14} alkylamines.	For use only as an adjuvant at levels not to exceed 0.5 percent by weight of the lubricant.
Phosphoric acid, mono- and diisooctyl esters, reacted with <i>tert</i> -alkyl and (C_{12} - C_{14}) primary amines (CAS Reg. No. 68187-67-7).	For use only as a corrosion inhibitor or rust preventative in lubricants at a level not to exceed 0.5 percent by weight of the lubricant.

§ 178.3620

21 CFR Ch. I (4-1-98 Edition)

which it contacts food does not exceed 0.002 inch.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 54 FR 24898, June 12, 1989]

§ 178.3620 Mineral oil.

Mineral oil may be safely used as a component of nonfood articles intended for use in contact with food, subject to the provisions of this section:

(a) White mineral oil meeting the specifications prescribed in § 172.878 of this chapter may be used as a component of nonfood articles provided such use complies with any applicable limitations in parts 170 through 189 of this chapter. The use of white mineral oil in or on food itself, including the use of white mineral oil as a protective coating or release agent for food, is subject to the provisions of § 172.878 of this chapter.

(b) Technical white mineral oil identified in paragraph (b)(1) of this section may be used as provided in paragraph (b)(2) of this section.

(1) Technical white mineral oil consists of specially refined distillates of virgin petroleum or of specially refined distillates that are produced synthetically from petroleum gases. Technical white mineral oil meets the following specifications:

(i) Saybolt color 20 minimum as determined by ASTM method D156-82, "Standard Test Method for Saybolt Color of Petroleum Products (Saybolt Chromometer Method)," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(ii) Ultraviolet absorbance limits as follows:

Wavelength (mμ)	Maximum absorbance per centimeter optical pathlength
280 to 289	4.0
290 to 299	3.3
300 to 329	2.3
330 to 350	0.8

Technical white mineral oil containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application to mineral oil under "Specification" on page 66 of the "Journal of the Association of Official Agricultural Chemists," Volume 45 (February 1962) (which is incorporated by reference; copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408), disregarding the last two sentences of that procedure and substituting therefor the following: Determine the absorbance of the mineral oil extract in a 10-millimeter cell in the range from 260-350 mμ, inclusive, compared to the solvent control. If the absorbance so measured exceeds 2.0 at any point in range 280-350 mμ, inclusive, dilute the extract and the solvent control, respectively, to twice their volume with dimethyl sulfoxide and remeasure the absorbance. Multiply the remeasured absorbance values by 2 to determine the absorbance of the mineral oil extract per centimeter optical pathlength.

(2) Technical white mineral oil may be used wherever mineral oil is permitted for use as a component of nonfood articles complying with §§ 175.105, 176.200, 176.210, 177.2260, 177.2600, and 177.2800 of this chapter and §§ 178.3570 and 178.3910.

(3) Technical white mineral oil may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

(c) Mineral oil identified in paragraph (c)(1) of this section may be used as provided in paragraph (c)(2) of this section.

(1) The mineral oil consists of virgin petroleum distillates refined to meet the following specifications:

(i) Initial boiling point of 450 °F minimum.

(ii) Color 5.5 maximum as determined by ASTM method D1500-82, "Standard

Test Method for ASTM Color of Petroleum Products (ASTM Color Scale)," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section.

(iii) Ultraviolet absorbance limits as follows as determined by the analytical method described in paragraph (c)(3) of this section:

Wavelength (mμ)	Maximum absorbance per centimeter optical pathlength
280 to 289	0.7
290 to 299	0.6
300 to 359	0.4
360 to 400	.09

(2) The mineral oil may be used whenever mineral oil is permitted for use as a component of nonfood articles complying with §§175.105 and 176.210 of this chapter and §178.3910 (for use only in rolling of metallic foil and sheet stock), §§176.200, 177.2260, 177.2600, and 177.2800 of this chapter.

(3) The analytical method for determining ultraviolet absorbance limit is as follows:

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of oil samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir. 500-milliliter capacity, equipped with a 24/40 standard taper male fitting at the bottom and a suitable ball-joint at the

top for connecting to the nitrogen supply. The male fitting should be equipped with glass hooks.

Chromatographic tube. 180 millimeters in length, inside diameter to be 15.7 millimeters ± 0.1 millimeter, equipped with a coarse, fritted-glass disc, a tetrafluoroethylene polymer stopcock, and a female 24/40 standard tapered fitting at the opposite end. (Overall length of the column with the female joint is 235 millimeters.) The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2-inch diameter disk approximately $\frac{1}{16}$ -inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Suction flask. 250-milliliter or 500-milliliter filter flask.

Condenser. 24/40 joints, fitted with a drying tube, length optional.

Evaporation flask (optional). 250-milliliter or 500-milliliter capacity all-glass flask equipped with standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5,000 centimeter ± 0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1,000 centimeter ± 0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons—400 millimicrons with spectral slit width of 2 millimicrons or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ± 0.01 at 0.4 absorbance.

Absorbance accuracy¹ ± 0.05 at 0.4 absorbance.

Wavelength accuracy, ± 1.0 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

¹As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, acetone, and methyl alcohol designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen (a loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and *n*-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 25 milliliters volume. Determine the absorbance in the 5-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimeter path length between 280 and 400 mμ. For methyl alcohol this absorbance value shall be 0.00.

Isooctane (2,2,4-trimethylpentane). Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Company, Baltimore, Maryland, or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

Benzene, A.C.S. reagent grade. Use 150 milliliters for the test. Purify, if necessary, by distillation or otherwise.

Acetone, A.C.S. reagent grade. Use 200 milliliters for the test. Purify, if necessary, by distillation.

Eluting mixtures:

1. **10 percent benzene in isooctane.** Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask and adjust to volume with isooctane, with mixing.

2. **20 percent benzene in isooctane.** Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask and adjust to volume with isooctane, with mixing.

3. **Acetone-benzene-water mixture.** Add 20 milliliters of water to 380 milliliters of acetone and 200 milliliters of benzene, and mix.

***n*-Hexadecane, 99-percent olefin-free.** Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference point between 280 mμ-400 mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Methyl alcohol, A.C.S. reagent grade. Use 10.0 milliliters of methyl alcohol. Purify, if necessary, by distillation.

Dimethyl sulfoxide. Spectrophotometric grade (Crown Zellerbach Corporation, Camas, Washington, or equivalent). Absorbance (1-centimeter cell, distilled water reference, sample completely saturated with nitrogen).

Wavelength	Absorbance (maximum)
281.5	1.00
270	.20
275	.09
280	.08
300	.015

There shall be no irregularities in the absorbance curve within these wavelengths.

Phosphoric acid, 85 percent A.C.S. reagent grade.

Sodium borohydride, 98 percent.

Magnesium oxide (Sea Sorb 43, Food Machinery Company, Westvaco Division, distributed by chemical supply firms, or equivalent). Place 100 grams of the magnesium oxide in a large beaker, add 700 milliliters of distilled water to make a thin slurry, and heat on a steam bath for 30 minutes with intermittent stirring. Stir well initially to insure that all the adsorbent is completely wetted. Using a Buchner funnel and a filter paper (Schleicher & Schuell No. 597, or equivalent) of suitable diameter, filter with suction. Continue suction until water no longer drips from the funnel. Transfer the adsorbent to a glass trough lined with aluminum foil (free from rolling oil). Break up the magnesia with a clean spatula and spread out the adsorbent on the aluminum foil in a layer about 1 centimeter to 2 centimeters thick. Dry for 24 hours at 160 °C ± 1 °C. Pulverize the magnesia with mortar and pestle. Sieve the pulverized adsorbent between 60-180 mesh. Use the magnesia retained on the 180-mesh sieve.

Celite 545. Johns Mansville Company, diatomaceous earth, or equivalent.

Magnesium oxide-Celite 545 mixture (2+1) by weight. Place the magnesium oxide (60-180 mesh) and the Celite 545 in 2 to 1 proportions, respectively, by weight in a glass-stoppered flask large enough for adequate mixing. Shake vigorously for 10 minutes. Transfer the mixture to a glass trough lined with aluminum foil (free from rolling oil)

and spread it out on a layer about 1 centimeter to 2 centimeters thick. Reheat the mixture at $160^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 2 hours, and store in a tightly closed flask.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter course, fritted-glass funnel or in a 65-millimeter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter path length between 280 m μ and 400 m μ when tested as prescribed under "Organic solvents." Usually three portions of wash solvent are sufficient.

Before proceeding with analysis of a sample, determine the absorbance in a 5-centimeter path cell between 250 millimicrons and 400 millimicrons for the reagent blank by carrying out the procedure, without an oil sample, recording the spectra after the extraction stage and after the complete procedure as prescribed. The absorbance per centimeter pathlength following the extraction stage should not exceed 0.02 in the wavelength range from 280 m μ to 400 m μ ; the absorbance per centimeter pathlength following the complete procedure should not exceed 0.02 in the wavelength range from 280 m μ to 400 m μ . If in either spectrum the characteristic benzene peaks in the 250 m μ -260 m μ region are present, remove the benzene by the procedure under "Organic solvents" and record absorbance again.

Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isooctane and shake to pre-equilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

Weigh a 20-gram sample of the oil and transfer to a 500-milliliter separatory funnel containing 100 milliliters of pre-equilibrated sulfoxide-phosphoric acid mixture. Complete the transfer of the sample with small portions of pre-equilibrated isooctane to give a total volume of the oil and solvent of 75 milliliters. Shake the funnel vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 30 milliliters of pre-equilibrated isooctane. After separation of liquid phases, carefully draw off lower layer into the first 250-milliliter separatory funnel and wash in tandem with the 30-milliliter portions of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1

minute. Repeat the extraction operation with two additional portions of the sulfide-acid mixture and wash each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2-liter) containing 480 milliliters of distilled water; mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second separatory funnel (preferably 2-liter) and repeat the extraction with 80 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 80-milliliter extractives three times with 100-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see Sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80-milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20-milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Quantitatively transfer the residue with isooctane to a 200-milliliter volumetric flask, make to volume, and mix. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to isooctane as reference between 280 m μ -400 m μ (take care to lose none of the solution in filling the sample cell). Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without an oil sample. If the corrected absorbance does not exceed the limits prescribed in this paragraph, the oil meets the ultraviolet absorbance specifications. If the corrected absorbance per centimeter pathlength exceeds the limits prescribed in this paragraph, proceed as follows: Quantitatively transfer the isooctane solution to a 125-milliliter flask equipped with 24/40 joint, and evaporate the isooctane on the steam bath under a stream of nitrogen to a volume of 1 milliliter of hexadecane. Add 10 milliliters of methyl alcohol and approximately 0.3 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere. A measuring dipper may be

used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the borohydride is dissolved, and allow to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this period, disconnect the flask and evaporate the methyl alcohol on the steam bath under nitrogen until the sodium borohydride begins to come out of the solution. Then add 10 milliliters of isooctane and evaporate to a volume of about 2-3 milliliters. Again, add 10 milliliters of isooctane and concentrate to a volume of approximately 5 milliliters. Swirl the flask repeatedly to assure adequate washing of the sodium borohydride residues.

Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weigh out 14 grams of the 2:1 magnesium oxide-Celite 545 mixture and pour the adsorbent mixture into the chromatographic tube in approximately 3-centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. Loosen the topmaforementioned rate. Just before the solvent mixture reaches adsorbent level, add 25 milliliters of 20 percent benzene in isooctane to the reservoir and continue the percolation at 2-3 milliliters per minute until all this solvent mixture has been removed from the column. Discard all the elution solvents collected up to this point. Add 300 milliliters of the acetone-benzene-water mixture to the reservoir and percolate through the column to eluate the polynuclear compounds. Collect the eluate in a clean 1-liter separatory funnel. Allow the column to drain until most of the solvent mixture is removed. Wash the eluate three times with 300-milliliter portions of distilled water, shaking well for each wash. (The addition of small amounts of sodium chloride facilitates separation.) Discard the aqueous layer after each wash. After the final separation, filter the residual benzene through anhydrous sodium sulfate pre-washed with benzene (see Sodium sulfate under "Reagents and Materials" for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the separatory funnel with two additional 20-milliliter portions of benzene which are also filtered through the sodium sulfate. Add 1 milliliter of *n*-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under "Organic solvents." Quantitatively transfer the residue with isooctane to a 200-milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 1-centimeter pathlength cells compared to

isooctane as reference between 250 mμ-400 mμ. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without an oil sample. If either spectrum shows the characteristic benzene peaks in the 250 mμ-260 mμ region, evaporate the solution to remove benzene by the procedure under "Organic solvents." Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 200-milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits proposed in this paragraph, the oil meets the proposed ultraviolet absorbance specifications.

(d) Mineral oil identified in paragraph (d)(1) of this section may be used as provided in paragraph (d)(2) of this section.

(1) The mineral oil consists of virgin petroleum distillates refined to meet the following specifications:

(i) Distillation endpoint at 760 millimeters pressure not to exceed 371 °C, with a maximum residue not to exceed 2 percent, as determined by ASTM method D86-82, "Standard Method for Distillation of Petroleum Products," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section.

(ii) Ultraviolet absorbance limits as follows as determined by the method described in paragraph (d)(3) of this section.

Wavelength (mμ)	Maximum absorbance per centimeter optical pathlength
280 to 299	2.3
300 to 319	1.2
320 to 3598
360 to 4003

(iii) Pyrene content not to exceed a maximum of 25 parts per million as determined by the method described in paragraph (d)(3) of this section.

(2) The mineral oil may be used only in the processing of jute fiber employed in the production of textile bags intended for use in contact with the following types of food: Dry grains and dry seeds (for example, beans, peas, rice, and lentils); whole root crop vegetables of the types identified in 40 CFR 180.34(f); unshelled and shelled nuts (including peanuts); and dry animal feed. The finished processed jute fiber shall

contain no more than 6 percent by weight of residual mineral oil.

(3) The analytical method for determining ultraviolet absorbance limits and pyrene content is as follows:

I. *Apparatus*. A. Assorted beakers, separatory funnels fitted with tetrafluoroethylene polymer stopcocks, and graduated cylinders.

B. Volumetric flasks, 200-milliliter.

C. A chromatographic column made from nominal 1.3 centimeters outside diameter \times 75 centimeters glass tubing tapered at one end and joined to a 2-millimeter-bore tetrafluoroethylene polymer stopcock. The opposite end is flanged and joined to a female 24/40 standard taper fitting. This provides for accommodating the 500-milliliter reservoir described in item I.E below.

D. A chromatographic column made from nominal 1.7 centimeters outside diameter \times 115 centimeters glass tubing tapered at one end and joined to a 2-millimeter-bore tetrafluoroethylene polymer stopcock. The opposite end is flanged and joined to a 2.5 centimeters outside diameter \times 9.0 centimeters glass tube having a female 24/40 standard taper fitting. This provides for accommodating the 500-milliliter reservoir described in item I.E below.

E. A 500-milliliter reservoir having a 24/40 standard taper male fitting at bottom and a suitable ball joint at the top for connecting to the nitrogen supply. The female fitting of the chromatographic columns described in items I.C and D above and the male fitting of the reservoir described in this item E should both be equipped with glass hooks.

(NOTE: Rubber stoppers are not to be used. Stopcock grease is not to be used on ground-glass joints in this method.)

F. A spectrophotometer equipped to automatically record absorbance of liquid samples in 1-centimeter pathlength cells in the spectral region of 280-400 m μ with a spectral slit width of 2 m μ or less. At an absorbance level of about 0.4, absorbance measurements shall be repeatable within ± 0.01 and accurate within ± 0.05 . Wavelength measurements shall be repeatable with ± 0.2 m μ and accurate within ± 1.0 m μ . Instrument operating conditions are selected to realize this performance under dynamic (automatic) recording operations. Accuracy of absorbance measurements are determined at 290, 345, and 400 m μ , using potassium chromate as the reference standard. (National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, 1949.)

G. Two fused quartz cells having pathlengths of 1.00 ± 0.005 centimeter or better.

II. *Purity of reagents and materials*. Reagent-grade chemicals shall be used in all tests. It is further specified that each chemical shall

be tested for purity in accordance with the instruction given under "Reagents and Materials" in III below. In addition, a blank run by the procedure shall be made on each purified lot of reagents and materials. Unless otherwise indicated, references to water shall be understood to mean distilled water.

III. *Reagents and materials*—A. *Organic solvents*. All solvents used throughout the procedure shall meet the specifications and tests described in this section III. The isooctane, benzene, cyclohexane, nitromethane, and *n*-hexadecane designated shall pass the following test: To the specified quantity of solvent in a 150-milliliter beaker, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains (to the residue from benzene and nitromethane add a 10-milliliter portion of purified isooctane, re-evaporate, and repeat once to insure complete removal of solvent). Dissolve the 1 milliliter of *n*-hexadecane residue in isooctane and make to 10-milliliter volume. Determine the absorbance in 1.0-centimeter pathlength cells compared to water as reference. The absorbance of the solution of solvent residue shall not exceed 0.05 between 280 and 400 m μ .

1. *Isooctane* (2,2,4-trimethylpentane). Use 240 milliliters for the above test. Purify, if necessary, by passage through a column of activated silica gel.

2. *Benzene*. Use 200 milliliters for the above test. Purify, if necessary, by distillation or otherwise.

3. *Cyclohexane*. Use 70 milliliters for the above test. Purify, if necessary, by distillation, silica gel percolation, or otherwise.

4. *Nitromethane*. Use 125 milliliters for the above test. Purify, if necessary, by distillation or otherwise.

5. *n-Hexadecane*. Determine the absorbance on this solvent directly. Purify, if necessary, by silica gel percolation or otherwise.

B. *Other materials*—1. *Pyrene standard reference*. Pyrene, reagent grade, melting point range 150-152 °C. (Organic Chemical 3627, Eastman Kodak Co., Rochester, N.Y., or equivalent). The standard reference absorbance is the absorbance at 334 millimicrons of a standard reference solution of pyrene containing a concentration of 1.0 milligram per liter in purified isooctane measured against isooctane of the same spectral purity in 1.0-centimeter cells. (This absorbance will be approximately 0.28.)

2. *Chrysene solution*. Prepare a solution at a concentration of 5.0 milligrams per liter by dissolving 5.0 milligrams of chrysene in purified isooctane in a 1-liter volumetric flask. Adjust to volume with isooctane.

3. *Nitrogen gas*. Water pumped or equivalent purity, cylinder with regulator, and valve control flow at 5 p.s.i.

4. *Silica gel*, 100-200 mesh (Davison Chemical, Baltimore, Md., Grade 923, or equivalent), purified and activated by the following procedure: Place about 1 kilogram of silica gel in a large column and wash with contaminant-free benzene until a 200-milliliter sample of the benzene coming off the column will pass the ultraviolet absorption test for benzene. This test is performed as stipulated under "Organic solvents" in A under III above. When the silica gel has been sufficiently cleaned, activate the gel before use by placing the 1-kilogram batch in a shallow container in a layer no greater than 1 inch in depth and heating in an oven (Caution! Explosion Hazard) at 130 °C. for 16 hours, and store in a vacuum desiccator. Reheating about once a week is necessary if the silica gel is repeatedly removed from the desiccator.

5. *Aluminum oxide* (Aluminum Co. of America, Grade F-20, or equivalent grade), 80-200 mesh, purified and activated by the following procedure: Place about 1 kilogram of aluminum oxide in a large column and wash with contaminant-free benzene until a 200-milliliter sample of the benzene coming off the column will pass the ultraviolet absorption test for benzene. This test is performed as stipulated under "Organic solvents" in A under III above. (Caution! Remove Benzene From Adsorbent Under Vacuum To Minimize Explosion Hazard in Subsequent Heating!) When the aluminum oxide has been sufficiently cleaned and freed of solvent, activate it before use by placing the 1-kilogram batch in a shallow container in a layer no greater than 1 inch in depth. Heat in an oven at 130 °C for 16 hours. Upon removal from heat, store at atmospheric pressure over 80 percent (by weight) sulfuric acid in a desiccator for at least 36 hours before use. This gives aluminum oxide with between 6 to 9.5 percent volatiles. This is determined by heating a weighed sample of the prepared aluminum oxide at 2,000 °F for 2 hours and then quickly reweighing. To insure the proper adsorptive properties of the aluminum oxide, perform the following test:

a. Weigh 50 grams \pm 1 gram of the activated aluminum oxide and pack into the chromatographic column (1.3 centimeters \times 75 centimeters) described under "Apparatus" in C under I above. Use glass wool at the column exit to prevent the aluminum oxide from passing through the column.

b. Place a 250-milliliter graduated cylinder under the column to measure the amount of eluate coming from the column.

c. Prewet the aluminum oxide by passing 40 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off the column is between 1.5 to 2.5 milliliters per minute.

d. Just prior to the last of the isooctane reaching the top of the aluminum oxide bed,

add 10 milliliters of the isooctane solution containing 5.0 milligrams of chrysene per liter.

e. Continue percolation until the isooctane is just above the aluminum oxide. Then add 200 milliliters of a mixture of benzene and isooctane (33% percent benzene and 66% percent isooctane by volume) to the reservoir and continue percolation.

f. Continue percolation, collecting the eluates (40 milliliters of the prewet solution, 10 milliliters of the sample solution, and 200 milliliters of the gradient solution) in the 250-milliliter graduated cylinder until the level of the gradient solution is just above the aluminum oxide. Add 200 milliliters of the eluting solution of benzene and isooctane (90 percent benzene and 10 percent isooctane by volume) to the column and continue collecting until a total of 250 milliliters of solution has been obtained. This may be discarded. Now begin to collect the final eluate.

g. Place a 100-milliliter graduated cylinder under the column and continue the percolation until a 100-milliliter eluate has been obtained.

h. Measure the amount of chrysene in this 100-milliliter fraction by ultraviolet analysis. If the aluminum oxide is satisfactory, more than 80 percent of the original amount of chrysene should be found in this fraction. (NOTE: If the amount of chrysene recovered is less than 80 percent, the original batch of aluminum oxide should be sieved between 100-160 mesh. Activation and testing of this sieved batch should indicate a satisfactory aluminum oxide for use.)

IV. *Sampling*. Precautions must be taken to insure that an uncontaminated sample of the mineral oil is obtained since ultraviolet absorption is very sensitive to small amounts of extraneous material contaminating the sample through careless handling.

V. *Procedure*. A. *Blank*. Before proceeding with the analysis of a sample, determine the absorbance of the solvent residues by carrying out the procedure without a sample.

B. *Sample*. 1. Weigh out 20.0 grams \pm 0.1 gram of the mineral oil into a beaker and transfer to a 250-milliliter separatory funnel fitted with a tetrafluoroethylene polymer stopcock, using enough cyclohexane (25 milliliters) to give a final total volume of 50 milliliters (mineral oil plus cyclohexane).

2. Add 25 milliliters of nitromethane saturated with cyclohexane and shake by hand vigorously for 3 minutes. Recover the lower nitromethane layer in a 150-milliliter beaker containing 1 milliliter of *n*-hexadecane and evaporate on the steam bath under nitrogen. Repeat the extraction four more times, recovering each extract in the 150-milliliter beaker. Exercise care not to fill the beaker to such a capacity that solvent losses may occur. Evaporate the combined nitromethane extracts to 1 milliliter of *n*-hexadecane residue containing the

nitromethane-soluble mineral oil extractions. (NOTE: Complete removal of the nitromethane is essential. This can be assured by two successive additions of 5 milliliters of isooctane and reevaporation.)

3. Remove the beaker from the steam bath and allow to cool.

4. Weigh 50 grams \pm 1 gram of activated aluminum oxide and pack into the chromatographic column (1.3 centimeters \times 75 centimeters) described under "Apparatus" in C under I above. (NOTE: A small plug of glass wool is placed at the column exit to prevent the aluminum oxide from passing through the column. After adding aluminum oxide, tap the column lightly to remove air voids. All percolations using aluminum oxide are performed under nitrogen pressure. The 500-milliliter reservoir described under "Apparatus" in E under I above is to be used to hold the elution solvents.)

5. Prewet the column by adding 40 milliliters of isooctane to the column. Adjust nitrogen pressure so that rate of descent of the isooctane coming off the column is 2.0 to 3.0 milliliters per minute. Be careful to maintain the level of solvent in the reservoir to prevent air from entering the aluminum oxide bed. New or additional solvent is added just before the last portion of the previous solvent enters the bed. To minimize possible photo-oxidation effects, the following procedures (steps 6 through 18) shall be carried out in subdued light.

6. Before the last of the isooctane reaches the top of the aluminum oxide bed, release the nitrogen pressure and turn off the stopcock on the column. Transfer the *n*-hexadecane residue from the 150-milliliter beaker from procedure step 3 above onto the column, using several washes of isooctane (total volume of washes should be no greater than 10-15 milliliters).

7. Open the stopcock and continue percolation until the isooctane is about 1 centimeter above the top of the aluminum oxide bed. Add 200 milliliters of isooctane to the reservoir, and continue the percolation at the specified rate.

8. Just before the isooctane surface reaches the top of the aluminum oxide bed, add 200 milliliters of a mixture of benzene and isooctane (33% percent benzene and 66% percent isooctane by volume) to the reservoir, and continue the percolation.

9. Just before the surface of this mixture reaches the top of the aluminum oxide bed, release the nitrogen pressure, turn off the stopcock, and discard all the elution solvents collected up to this point.

10. Add to the reservoir 300 milliliters of a mixture of benzene and isooctane (90 percent benzene and 10 percent isooctane by volume), place a 25-milliliter graduated cylinder under the column, continue the percolation until 20 milliliters of eluate has been collected, and then discard the eluate.

11. At this point, place a clean 250-milliliter Erlenmeyer flask under the column. Continue the percolation and collect all the remaining eluate.

(NOTE: Allow the column to drain completely. An increase in the nitrogen pressure may be necessary as the last of the solvent comes off the column.)

12. Place 1 milliliter of *n*-hexadecane into a 150-milliliter beaker. Place this onto a steam bath under a nitrogen stream and transfer in small portions the eluate from step 11 above. Wash out the Erlenmeyer flask with small amounts of benzene and transfer to the evaporation beaker. Evaporate until only 1 milliliter of hexadecane residue remains. (NOTE: Complete removal of the benzene is essential. This can be assured by two successive additions of 5 milliliters of isooctane and reevaporation.)

13. Remove the beaker from the steam bath and cool.

14. Place a sample of 113.5 grams activated 100-200-mesh silica gel in a 500-milliliter glass-stoppered Erlenmeyer flask. Add to the silica gel 46.2 grams (41 milliliters) of nitromethane. Stopper and shake the flask vigorously until no lumps of silica gel are observed and then shake occasionally during a period of 1 hour. The resultant nitromethane-treated silica gel is 29 weight-percent nitro-methane and 71 weight-percent silica gel.

15. Place a small plug of glass wool in the tapered end of the 1.7 centimeters outside diameter \times 115 centimeters column, described under "Apparatus" in D of I above, adjacent to the stopcock to prevent silica gel from passing through the stopcock. Pack the nitromethane-treated silica gel into the column, tapping lightly. The resultant silica gel bed should be about 95 centimeters in depth. Place into a flask 170 milliliters of isooctane saturated with nitromethane.

16. Place a 100-milliliter graduated cylinder under the column and transfer the residue from the beaker in procedure step 13 above with several washes of the 170 milliliters of isooctane, saturated with nitromethane, onto the top of the column. (Total volume of washes should be no greater than 10 to 15 milliliters.) Permit isooctane solution to enter the silica gel bed until the liquid level is at the top bed level. Place the remaining amount of the 170 milliliters of isooctane, saturated with nitromethane, in the reservoir above the bed for percolation through the silica gel. Apply nitrogen pressure to the top of the column, adjusting the pressure so that the isooctane is collected at the rate of 2.5 to 3.5 milliliters per minute, and percolate isooctane through the bed until a quantity of 75.0 milliliters of eluate is collected. Discard the 75 milliliters of eluate. Turn off the stopcock and add 250 milliliters of benzene to the reservoir above the bed.

Use a 400-milliliter beaker to collect the remaining eluate.

17. Open the stopcock, renew the pressure, and percolate the remaining isooctane and benzene through the column eluting the remaining aromatics. Transfer the eluate in small portions from the 400 milliliter beaker to a 150-milliliter beaker containing 1 milliliter of *n*-hexadecane and evaporate on the steam bath under nitrogen. Rinse the 400-milliliter beaker well with small portions of isooctane to obtain a complete transfer.

(NOTE: Complete removal of the nitromethane and benzene is essential. This can be assured by successive additions of 5 milliliters of isooctane and reevaporation.)

18. Transfer the residue with several washes of isooctane into a 200-milliliter volumetric flask. Add isooctane to mark.

19. Record the spectrum of the sample solution in a 1-centimeter cell compared to isooctane from 270 to 400 mμ. After making necessary corrections in the spectrum for cell differences and for the blank absorbance, record the maximum absorbance in each of the wavelength intervals (mμ), 280-299, 300-319, 320-359, 360-400.

a. If the spectrum then shows no discernible peak corresponding to the absorbance maximum of the pyrene reference standard solution at 334 mμ, the maximum absorbances in the respective wavelength intervals recorded shall not exceed those prescribed in paragraph (d)(1)(ii) of this section.

b. If such a peak is evident in the spectrum of the sample solution, and the spectrum as a whole is not incompatible with that of a pyrene contaminant yielding such a peak of the observed absorbance, calculate the concentration of pyrene that would yield this peak (334 m) by the base-line technique described in ASTM method E169-63 (Reapproved 1981), "Standard Recommended Practices for General Techniques of Ultraviolet Quantitative Analysis," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section. Correct each of the maximum absorbances in the respective specified wavelength intervals by subtracting the absorbance due to pyrene, determined as follows:

$$\text{Absorbance due to pyrene} = \frac{C_p \times S_a}{S_p}$$

where:

C_p=Calculated concentration of pyrene in sample solution;

S_p=Concentration of pyrene reference standard solution in same units of concentration;

S_a=Absorbance of pyrene reference standard solution at wavelength of maximum absorbance of sample solution in the respective specified wavelength intervals.

Also calculate the pyrene content of the oil sample in parts per million as follows:

$$\text{Pyrene content (p.p.m.)} = \frac{(200/1000) \times C}{20/1000} = 10C$$

where:

C=Calculated concentration of pyrene in milligrams per liter of sample solution.

c. The pyrene content so determined shall not exceed 25 p.p.m. The maximum absorbances corrected for pyrene content as described in this step 19 for each of the specified wavelength intervals shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

d. If the spectrum as a whole of the sample solution is in any respect clearly incompatible with the presence of pyrene as the source of the peak at 334 mμ, then the maximum absorbances in the respective wavelength intervals without correction for any assumed pyrene content shall not exceed the limits prescribed in paragraph (d)(1)(ii) of this section.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 49 FR 10112, Mar. 19, 1984; 54 FR 24898, June 12, 1989]

§ 178.3650 Odorless light petroleum hydrocarbons.

Odorless light petroleum hydrocarbons may be safely used, as a component of nonfood articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) The additive is a mixture of liquid hydrocarbons derived from petroleum or synthesized from petroleum gases. The additive is chiefly paraffinic, isoparaffinic, or naphthenic in nature.

(b) The additive meets the following specifications:

- (1) Odor is faint and not kerosenic.
- (2) Initial boiling point is 300 °F minimum.
- (3) Final boiling point is 650 °F maximum.

(4) Ultraviolet absorbance limits determined by method specified in § 178.3620(b)(1)(ii), as follows:

Wavelength (Mμ)	Maximum absorbance per centimeter optical pathlength
280 to 289	4.0
290 to 299	3.5
300 to 329	2.5

basic resins produced by the polymerization of vinyl fluoride.

(b) The poly(vinyl fluoride) basic resins have an intrinsic viscosity of not less than 0.75 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(1) *Solvent.* *N,N*-Dimethylacetamide, technical grade.

(2) *Solution.* Powdered resin and solvent are heated at 120 °C until the resin is dissolved.

(3) *Temperature.* Flow times of the solvent and solution are determined at 110 °C.

(4) *Viscometer.* Cannon-Ubbelohde size 50 semimicro dilution viscometer (or equivalent).

(5) *Calculation.* The calculation method used is that described in appendix X 1.3 (ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference; see paragraph (b) of this section for availability of the incorporation by reference) with the reduced viscosity determined for three concentration levels not greater than 0.5 gram per deciliter and extrapolated to zero concentration for intrinsic viscosity. The following formula is used for determining reduced viscosity:

$$\text{Reduced viscosity in terms of deciliters per gram} = \frac{t - t_0}{t_0 \times c}$$

where:

t=Solution efflux time.

*t*₀=Solvent efflux time.

c=Concentration of solution in terms of grams per deciliter.

[42 FR 14534, Mar. 15, 1977, as amended at 47 FR 11839, Mar. 19, 1982; 49 FR 10107, Mar. 19, 1984]

§ 175.300 Resinous and polymeric coatings.

Resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in

producing, manufacturing, packaging, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) The coating is applied as a continuous film or enamel over a metal substrate, or the coating is intended for repeated food-contact use and is applied to any suitable substrate as a continuous film or enamel that serves as a functional barrier between the food and the substrate. The coating is characterized by one or more of the following descriptions:

(1) Coatings cured by oxidation.

(2) Coatings cured by polymerization, condensation, and/or cross-linking without oxidation.

(3) Coatings prepared from prepolymerized substances.

(b) The coatings are formulated from optional substances that may include:

(1) Substances generally recognized as safe in food.

(2) Substances the use of which is permitted by regulations in this part or which are permitted by prior sanction or approval and employed under the specific conditions, if any, of the prior sanction or approval.

(3) Any substance employed in the production of resinous and polymeric coatings that is the subject of a regulation in subchapter B of this chapter and conforms with any specification in such regulation. Substances named in this paragraph (b)(3) and further identified as required:

(i) Drying oils, including the triglycerides or fatty acids derived therefrom:

Beechnut.
Candlenut.
Castor (including dehydrated).
Chinawood (tung).
Coconut.
Corn.
Cottonseed.
Fish (refined).
Hempseed.
Linseed.
Oiticica.
Perilla.
Poppyseed.
Pumpkinseed.
Safflower.
Sesame.
Soybean.
Sunflower.
Tall oil.

Walnut.

The oils may be raw, heat-bodied, or blown. They may be refined by filtration, degumming, acid or alkali washing, bleaching, distillation, partial dehydration, partial polymerization, or solvent extraction, or modified by combination with maleic anhydride.

(ii) Reconstituted oils from triglycerides or fatty acids derived from the oils listed in paragraph (b)(3)(i) of this section to form esters with:

Butylene glycol.
Ethylene glycol.
Pentaerythritol.
Polyethylene glycol.
Polypropylene glycol.
Propylene glycol.
Sorbitol.
Trimethylol ethane.
Trimethylol propane.

(iii) Synthetic drying oils, as the basic polymer:

Butadiene and methylstyrene copolymer.
Butadiene and styrene copolymer, blown or unblown.
Maleic anhydride adduct of butadiene styrene.
Polybutadiene.

(iv) Natural fossil resins, as the basic resin:

Copal.
Damar.
Elemi.
Gilsonite.
Glycerol ester of damar, copal, elemi, and sandarac.
Sandarac.
Shellac.
Utah coal resin.

(v) Rosins and rosin derivatives, with or without modification by polymerization, isomerization, incidental decarboxylation, and/or hydrogenation, as follows:

(a) Rosins, refined to color grade of K or paler:

Gum rosin.
Tall oil rosin.
Wood rosin.

(b) Rosin esters formed by reacting rosin (paragraph (b)(3)(v)(a) of this section) with:

4,4'-sec-Butylidenediphenol-epichlorohydrin (epoxy).
Diethylene glycol.
Ethylene glycol.

Glycerol.

4,4'-Isopropylidenediphenol-epichlorohydrin (epoxy).

Methyl alcohol.

Pentaerythritol.

(c) Rosin esters (paragraph (b)(3)(v)(b) of this section) modified by reaction with:

Maleic anhydride.

o-, *m*-, and *p*-substituted phenol-formaldehydes listed in paragraph (b)(3)(vi) of this section.

Phenol-formaldehyde.

(d) Rosin salts:

Calcium resinate (limed rosin).

Zinc resinate.

(vi) Phenolic resins as the basic polymer formed by reaction of phenols with formaldehyde:

(a) Phenolic resins formed by reaction of formaldehyde with:

Alkylated (methyl, ethyl, propyl, isopropyl, butyl) phenols.

p-tert-Amylphenol.

4,4'-sec-Butylidenediphenol.

p-tert-Butylphenol.

o-, *m*-, and *p*-Cresol.

p-Cyclohexylphenol.

4,4'-Isopropylidenediphenol.

p-Nonylphenol.

p-Octylphenol.

3-Pentadecyl phenol mixture obtained from cashew nut shell liquid.

Phenol.

Phenyl *o*-cresol.

p-Phenylphenol.

Xylenol.

(b) Adjunct for phenolic resins: Aluminum butylate.

(vii) Polyester resins (including alkyd-type), as the basic polymers, formed as esters of acids listed in paragraph (b)(3)(vii) (a) and (b) of this section by reaction with alcohols in paragraph (b)(3)(vii) (c) and (d) of this section.

(a) Polybasic acids:

Adipic.

1,4-cyclohexanedicarboxylic (CAS Reg. No. 1076-0997-097).

Dimerized fatty acids derived from oils listed in paragraph (b)(3)(i) of this section.

Fumaric.

Isophthalic.

Maleic.

Orthophthalic.

Sebacic.

Terephthalic.

Terpene-maleic acid adduct.

Trimellitic.

(b) Salts:

Caprate.
Caprylate.
Dodecanoate.
Linoleate.
Naphthenate.
Neodecanoate.
Octoate (2-ethylhexoate).
Oleate.
Palmitate.
Resinate.
Ricinoate.
Stearate.
Tallate.

(xxiii) Waxes:

Paraffin, Type I.
Paraffin, Type II.
Polyethylene.
Sperm oil.
Spermaceti.

(xxiv) Plasticizers:

Acetyl tributyl citrate.
Acetyl triethyl citrate.
Butyl phthalyl butyl glycolate.
Butyl stearate.
p-tert-Butyl phenyl salicylate.
Dibutyl sebacate.
Diethyl phthalate.
Diisobutyl adipate.
Diisooctyl phthalate.
Epoxidized soybean oil (iodine number maximum 14; oxirane oxygen content 6% minimum), as the basic polymer.
Ethyl phthalyl ethyl glycolate.
2-Ethylhexyl diphenyl phosphate.
di-2-Ethylhexyl phthalate.
Glycerol.
Glyceryl monooleate.
Glyceryl triacetate.
Monoisopropyl citrate.
Propylene glycol.
Sorbitol.
Mono-, di-, and tristearyl citrate.
Triethyl citrate.
Triethylene glycol.
3-(2-Xenolyl)-1,2-epoxypropane.

(xxv) Release agents, as the basic polymer, when applicable:

N,N'-Dioleylethylenediamine (CAS Reg. No. 110-31-6) for use only in ionomeric resins complying with §177.1330 of this chapter and in ethylene vinyl acetate copolymers complying with §177.1350 of this chapter at a level not to exceed 0.0085 milligram per square centimeter (0.055 milligram per square inch) in the finished food-contact article.

N,N'-Distearoyl ethylenediamine.
Linoleic acid amide.
Oleic acid amide.
Palmitic acid amide.

Petrolatum.

Polyethylene wax.

Polyoxyethylene glycol monooleate (mol. wt. of the polyoxyethylene glycol moiety greater than 300).

Polytetrafluoroethylene.

Silicones (not less than 300 centistokes viscosity): Dimethylpolysiloxanes and/or methylphenylpolysiloxanes. The methylphenylpolysiloxanes contain not more than 2.0 percent by weight of cyclosiloxanes having up to and including 4 siloxy units.

Silicones (not less than 100 centistokes viscosity): Dimethylpolysiloxanes and/or methylphenylpolysiloxanes limited to use only on metal substrates. The methylphenylpolysiloxanes contain not more than 2.0 percent by weight of cyclosiloxanes having up to and including 4 siloxy units.

(xxvi) Colorants used in accordance with §178.3297 of this chapter.

(xxvii) Surface lubricants:

Cottonseed oil and other edible oils.
Dibutyl sebacate.
Diocetyl sebacate.
Glyceryl monostearate.
Lanolin.
Mineral oil, white.
Palm oil.
Paraffin, Type I.
Paraffin, Type II.
Petrolatum.
Stearic acid.

(xxviii) Silicones and their curing catalysts:

(a) Silicones as the basic polymer:

Siloxane resins originating from methyl hydrogen polysiloxane, dimethyl polysiloxane, and methylphenyl polysiloxane.

(b) Curing (cross-linking) catalysts for silicones (the maximum amount of tin catalyst used shall be that required to effect optimum cure but shall not exceed 1 part of tin per 100 parts of siloxane resins solids):

Dibutyltin dilaurate.
Stannous oleate.
Tetrabutyl titanate.

(xxix) Surface active agents:

Ethylene oxide adduct of 2,4,7,9-tetramethyl-5-decyn-4,7-diol (CAS Reg. No. 9014-85-1).
Poly(2-(diethylamino) ethyl methacrylate) phosphate (minimum intrinsic viscosity in water at 25 °C is not less than 9.0 deciliters per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference

175,390 Zinc-silicon dioxide matrix coatings
AUSTRIAN PAT. 21 U.S.C. 321, 342, 348, 379e.

(2) Substances permitted for use in adhesives by prior sanction or approval and employed under the specific conditions of use prescribed by such sanction or approval.

(3) Flavoring substances permitted for use in food by regulations in this part, provided that such flavoring substances are volatilized from the adher-

process.

**Support B—Substances for Use
Only as Components of Adhesives**

(a) Adhesives may be safely used as components of articles intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:

MS96, July 17, 1895]

Subpart A [Reserved]

Components of Adhesives

Adhesives.

Components of Coatings

Hot-melt strippable food coatings.

Partial phosphoric acid esters of poly-

**Poly(vinyl fluoride) resins.
Resinous and polymeric coatings.**

polyolefin films.

vinylidene chloride copolymer coat

Vinylidene chloride copolymer coat

Xylene-formaldehyde resins containing 4,4'-isobiphenylene

chlorohydrin epox

AUTHORITY: 21 U.S.C. 321, 342, 350, 355.

EDITORIAL NOTE: Nomenclature changes to the 1996 edition of 61 FR 14482, Apr. 2, 1996.

stances are volatilized from the adhesives during the packaging fabrication

**Support B—Substances for Use
Only as Components of Adhesives**

(a) Adhesives may be safely used as components of articles intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:

(1) The adhesive is prepared from one or more of the optional substances named in paragraph (c) of this section subject to any prescribed limitations.

(2) The adhesive is either separate from the food by a functional barrier or used subject to the following additional limitations:

(1) *In dry foods.* The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.

(11) *In fatty and aqueous foods.* (a) The quantity of adhesive that contacted packaged fatty and aqueous foods should not exceed the trace amount at seal and at the edge exposure between packages and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.

(b) Under normal, commercial use, the packaging seams or laminates will remain firmly bonded without visible separation.

(b) To assure that the label of the finished adhesive container shall bear the statement "Toxic adhesive".

(c) Subject to any regulation promulgated under section 409 of the Act which prescribes conditions of use for substances may be employed as constituents, nevertheless, the optional substances in the formulation of adhesives may include the following:

(1) Substances generally recognized as safe for use in food or food packaging.

(2) Substances permitted for use in adhesives by prior sanction or approval

and employed under the specific conditions of use prescribed by such sanction or approval.

(c) Flavoring substances permitted for use in food by regulations in this part, provided that such flavoring substances are volatilized from the adhesives during the packaging fabrication process.

(4) Color additives approved for use in food.

(5) Substances permitted for use in adhesives by other regulations in this subchapter and substances named in this subparagraph: *Provided, however*, That any substance named in this paragraph and covered by a specific regulation in this subchapter, must meet any specifications in such regulation.

[illegible]

Substances	Limitations
Itaconic acid. Japan wax. Kerosene. Lauroyl peroxide. Lauroyl sulfate salts: Ammonium. Magnesium. Potassium. Sodium. Lauryl alcohol. Lauryl pyridinium 5-chloro-2-mercaptobenzothiazole. Lignin calcium sulfonate. Lignin sodium sulfonate. Linoleamide (linoleic acid amide). Magnesium fluoride	For use only as bonding agent for aluminum foil, stabilizer, or preservative. Total fluoride from all sources not to exceed 1 percent by weight of the finished adhesives.
Magnesium glycerophosphate. Maleic acid. Maleic anhydride-diisobutylene copolymer, ammonium or sodium salt. Manganese acetate. Marine oil fatty acid soaps, hydrogenated. Melamine. Melamine-formaldehyde copolymer. 2-Mercaptobenzothiazole. 2-Mercaptobenzothiazole and dimethyl dithiocarbamic acid mixture, sodium salt. 2-Mercaptobenzothiazole, sodium or zinc salt	For use as preservative only. For use as preservative only.
Methacrylate-chromic chloride complex, ethyl or methyl ester. p-Menthane hydroperoxide. Methyl acetate. Methyl acetyl ricinoleate. Methyl alcohol (methanol). Methylcellulose. Methylene chloride. 4,4'-Methylenebis(2,6-di-tert-butylphenol). 2,2-Methylenebis (4-ethyl-6-tert-butylphenol). 2,2-Methylenebis (4-methyl-6-nonylphenol). 2,2-Methylenebis (4-methyl-6-tert-butylphenol). Methyl ethyl ketone. Methyl ethyl ketone-formaldehyde condensate. 2-Methylhexane 1-Methyl-2-hydroxy-4-isopropyl benzene. Methyl isobutyl ketone Methyl oleate. Methyl oleate-palmitate mixture. Methyl phthalyl ethyl glycolate. Methyl ricinoleate. Methyl salicylate. a-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 a methylstyrene to 3 vinyltoluene). Methyl tallowate. Mineral oil. Monochloroacetic acid. Monooctylidiphenylamine Montan wax. Morpholine. Myrsic acid-chromic chloride complex. Myristyl alcohol. Naphtha. Naphthalene, monosulfonated. Naphthalene sulfonic acid-formaldehyde condensate, sodium salt. α-Naphthylamine. α,α',α'',α'''-Neopentane tetrayltetrakis [omega-hydroxypoly (oxypropylene) (1-2 moles)], average molecular weight 400. Nitric acid. p-Nitrobiphenyl. Nitrocellulose. 2-Nitropropane. α-(p-Nonylphenyl)-omega-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 6-9 moles or 50 moles.	

§ 175.210

Tri(mixed mono- and dinonylphenyl) phosphite (which may contain not more than 1 percent by weight of triisopropanolamine).

(c) Acrylonitrile copolymers identified in this section shall comply with the provisions of §180.22 of this chapter.

[42 FR 14534, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977; 48 FR 15617, Apr. 12, 1983; 63 FR 3464, Jan. 23, 1998]

Subpart C—Substances for Use as Components of Coatings

§ 175.210 Acrylate ester copolymer coating.

Acrylate ester copolymer coating may safely be used as a food-contact surface of articles intended for packaging and holding food, including heating of prepared food, subject to the provisions of this section:

(a) The acrylate ester copolymer is a fully polymerized copolymer of ethyl acrylate, methyl methacrylate, and methacrylic acid applied in emulsion form to molded virgin fiber and heat-cured to an insoluble resin.

(b) Optional substances used in the preparation of the polymer and in the preparation and application of the emulsion may include substances named in this paragraph, in an amount not to exceed that required to accomplish the desired technical effect and subject to any limitation prescribed: *Provided, however,* That any substance named in this paragraph and covered by a specific regulation in subchapter B of this chapter must meet any specifications in such regulation.

List of substances	Limitations
Aluminum stearate. Ammonium lauryl sulfate. Borax	Not to exceed the amount required as a preservative in emulsion defoamer. Do.
Disodium hydrogen phosphate	
Formaldehyde. Glyceryl monostearate. Methyl cellulose. Mineral oil. Paraffin wax. Potassium hydroxide. Potassium persulfate. Tallow. Tetrasodium pyrophosphate. Titanium dioxide.	

21 CFR Ch. I (4-1-98 Edition)

(c) The coating in the form in which it contacts food meets the following tests:

(1) An appropriate sample when exposed to distilled water at 212 °F for 30 minutes shall yield total chloroform-soluble extractables not to exceed 0.5 milligram per square inch.

(2) An appropriate sample when exposed to *n*-heptane at 120 °F for 30 minutes shall yield total chloroform-soluble extractables not to exceed 0.5 milligram per square inch.

§ 175.230 Hot-melt strippable food coatings.

Hot-melt strippable food coatings may be safely applied to food, subject to the provisions of this section.

(a) The coatings are applied to and used as removable coatings for food.

(b) The coatings may be prepared, as mixtures, from the following substances:

(1) Substances generally recognized as safe in food.

(2) Substances identified in this subparagraph.

List of substances	Limitations
Acetylated monoglycerides	Complying with 172.828 of this chapter.
Cellulose acetate butyrate. Cellulose acetate propionate. Mineral oil, white	For use only as a component of hot-melt strippable food coatings applied to frozen meats and complying with § 172.878 of this chapter.

§ 175.250 Paraffin (synthetic).

Synthetic paraffin may be safely used as an impregnant in, coating on or component of coatings on articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) The additive is synthesized by the Fischer-Tropsch process from carbon monoxide and hydrogen, which are catalytically converted to a mixture of paraffin hydrocarbons. Lower molecular-weight fractions are removed by distillation. The residue is hydrogenated and may be further treated by percolation through activated charcoal. This mixture can be fractionated

§ 176.150

used to prevent the transfer of inks employed in printing and decorating paper and paperboard used for food packaging in accordance with the provisions of this section:

(a) The substances are applied to the nonfood contact, printed side of the paper or paperboard in an amount not greater than that required to accomplish the technical effect nor greater than any specific limitations, where such are provided.

(b) Anti-offset powders are prepared from substances that are generally recognized as safe in food, substances for which prior sanctions or approvals were granted and which are used in accordance with the specific provisions of such sanction or approval, and substances named in paragraph (c) of this section.

(c) The substances permitted are as follows:

Substances	Limitations
Carbon tetrachloride. Methyl hydrogen polysiloxanes. Industrial starch—modified Stannous oleate. Zinc-2-ethyl hexoate.	Complying with § 178.3520 of this chapter.

§ 176.150 Chelating agents used in the manufacture of paper and paperboard.

The substances named in paragraph (a) of this section may be safely used in the manufacture of paper and paperboard, in accordance with the conditions prescribed in paragraphs (b) and (c) of this section:

(a) Chelating agents:

List of substances	Limitations
Ammonium fructoheptonate. Ammonium glucoheptonate. Disodium ethylenediamine tetraacetate. Pentasodium salt of diethylenetriamine pentaacetate. Sodium fructoheptonate. Sodium glucoheptonate. Tetrasodium ethylenediamine tetraacetate. Trisodium N-hydroxyethyl ethylenediamine triacetate.	

(b) Any one or any combination of the substances named is used or intended for use as chelating agents.

(c) The substances are added in an amount not greater than that required

21 CFR Ch. I (4-1-98 Edition)

to accomplish the intended technical effect nor greater than any specific limitation, where such is provided.

§ 176.160 Chromium (Cr III) complex of N-ethyl-N-heptadecylfluoro-octane sulfonyl glycine.

The chromium (Cr III) complex of N-ethyl - N -heptadecylfluoro-octane sulfonyl glycine containing up to 20 percent by weight of the chromium (Cr III) complex of heptadecylfluoro-octane sulfonic acid may be safely used as a component of paper for packaging dry food when used in accordance with the following prescribed conditions.

(a) The food additive is used as a component of paper in an amount not to exceed 0.5 percent by weight of the paper.

(b)(1) The food-contact surface of the paper is overcoated with a polymeric or resinous coating at least 1/8-mil in thickness, that meets the provision of § 176.170; or

(2) The treated paper forms one or more plies of a paper in a multiwall bag and is separated from the food by at least one ply of packaging films or grease-resistant papers which serves as a functional barrier between the food additive and the food. Such packaging films or grease-resistant papers conform with appropriate food additive regulations.

(c) The labeling of the food additive shall contain adequate directions for its use to insure compliance with the requirements of paragraphs (a) and (b) of this section.

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

Substances identified in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packaging, processing, preparing, treating, packing, transporting, or holding aqueous and fatty foods, subject to the provisions of this section. Components of paper and paperboard in contact with dry food of the type identified under Type VIII of table 1 in paragraph (c) of this section are subject to the provisions of § 176.180.

(a) Substances identified in paragraph (a) (1) through (5) of this section may be used as components of the food-contact surface of paper and paperboard. Paper and paperboard products shall be exempted from compliance with the extractives limitations prescribed in paragraph (c) of this section: *Provided*, That the components of the food-contact surface consist entirely of one or more of the substances identified in this paragraph: *And provided further*, That if the paper or paperboard when extracted under the conditions prescribed in paragraph (c) of this section exceeds the limitations on extractives contained in paragraph (c) of this section, information shall be available from manufacturing records from which it is possible to determine that only substances identified in this para-

graph (a) are present in the food-contact surface of such paper or paperboard.

(1) Substances generally recognized as safe in food.

(2) Substances generally recognized as safe for their intended use in paper and paperboard products used in food packaging.

(3) Substances used in accordance with a prior sanction or approval.

(4) Substances that by regulation in parts 170 through 189 of this chapter may be safely used without extractives limitations as components of the uncoated or coated food-contact surface of paper and paperboard in contact with aqueous or fatty food, subject to the provisions of such regulation.

(5) Substances identified in this paragraph, as follows:

List of Substances	Limitations
Acetyl peroxide	For use only as polymerization catalyst.
Acrylamide-methacrylic acid-maleic anhydride copolymers containing not more than 0.2 percent of residual acrylamide monomer and having an average nitrogen content of 14.9 percent such that a 1 percent by weight aqueous solution has a minimum viscosity of 600 centipoises at 75 °F, as determined by LVG-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 30 r.p.m.	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard in such an amount that the finished paper and paperboard will contain the additive at a level not in excess of 0.05 percent by weight of dry fibers in the finished paper and paperboard.
Acrylamide-β-methacryloyloxyethyltrimethylammonium methyl sulfate copolymer resins containing not more than 10 molar percent of β-methacryloyloxyethyltrimethylammonium methyl sulfate and containing less than 0.2% of residual acrylamide monomer.	For use only as a retention aid and flocculant employed prior to the sheet-forming operation in the manufacture of paper and paperboard.
Acrylic acid, sodium salt copolymer with polyethyleneglycol allyl ether (CAS Reg. No. 86830-15-1).	For use only in paper mill boilers.
Acrylic acid copolymer with 2-acrylamido-2-methylpropane-sulfonic acid (CAS Reg. No. 40623-75-4) and/or its ammonium/alkali metal mixed salts. The copolymer is produced by polymerization of acrylic acid and 2-acrylamido-2-methylpropane-sulfonic acid in a weight ratio of 60/40, such that a 28 percent by weight aqueous solution of the polymer has a viscosity of 75-150 centipoises at 25 °C as determined by LV-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 60 r.p.m.	For use only as a scale inhibitor prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1.0 kilogram (2.2 pounds) of copolymer per 907 kilograms (1 ton) of dry paper and paperboard fibers.
Acrylonitrile polymer, reaction product with ethylenediamine sulfate having a nitrogen content of 22.5-25.0 percent (Kjeldahl dry basis) and containing no more than 0.075 percent monomer as ethylenediamine. The finished resin in a 24 percent by weight aqueous solution has a viscosity of 1,000-2,000 centipoises at 25 °C as determined by LVT-series Brookfield viscometer using a No. 4 spindle at 50 r.p.m. (or by other equivalent method).	For use only as a size promoter and retention aid at a level not to exceed 0.5 percent by weight of the dry paper and paperboard.
Acrylonitrile polymer with styrene, reaction product with ethylenediamine acetate, having a nitrogen content of 7.4-8.3 percent (Kjeldahl dry basis) and containing no more than 0.25 percent monomer as ethylenediamine.	1. For use only as a sizing material applied after the sheet-forming operation in the manufacture of paper and paperboard in such amount that the paper and paperboard will contain the additive at a level not in excess of 0.25 percent by weight of the dry paper and paperboard. 2. For use only as a sizing material applied prior to the sheet-forming operation in the manufacture of paper and paperboard in such amount that the paper and paperboard will contain the additive at a level not in excess of 1.0 percent by weight of the dry paper and paperboard.

List of Substances	Limitations
dimethylallylamine hydrochloride polymer with epichlorohydrin having a nitrogen content of 4.8 to 5.9 percent (Kjeldahl dry basis) such that a 20 percent by weight aqueous solution has a minimum viscosity of 30 centipoises and maximum viscosity of 100 centipoises at 25 °C, as determined by LVF Model Brookfield viscometer using a No. 1 spindle at 60 r.p.m. (or equivalent method).	For use only as a retention aid, flocculating agent, and wet-strength agent employed in the manufacture of paper and paperboard prior to the sheet-forming operation and limited to use at a level not to exceed 1.5 percent by weight of the dry paper and paperboard.
dimethyl naphthalene sulfonic acid-formaldehyde condensate, sodium salt.	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
dimethyl-N-(tail oil acyl) taurine, sodium salt (CAS Reg. No. 81791-41-1).	For use only to control scale formation in the manufacture of paper and paperboard prior to the sheet-forming operation at a level not to exceed 0.015 percent by weight of the dry paper and paperboard.
dimethyl oil, white.	For use only as an emulsifier for rosin based sizing at a level not to exceed 0.03 percent by weight of the finished dry paper and paperboard.
dimethyl, di-, tri-(1-methyl-1-phenylethyl)-phenol, ethoxylated, sulfated, ammonium salt with an average of 12 to 16 moles of ethylene oxide (CAS Reg. No. 68130-71-2).	
dimethylglycidyl ether.	
dimethylseed oil, sulfated, ammonium, potassium, or sodium salt.	
dimethylsulfone sulfonic acid-formaldehyde condensate, sodium salt.	For use only as an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation.
dimethylcellulose, 10.9-12.2% nitrogen.	
dimethyl acid, sulfated, ammonium, potassium, or sodium salt.	
dimethyl-N-stearoyl-ethylenediamine.	
dimethylamine.	
dimethylaldehyde.	For use only as setting agent for protein.
dimethyl acid, 4,4-bis [(gamma-omega-perfluoro-C ₈ -20-alkylthio) derivatives, compounds with diethanolamine (CAS Reg. No. 71608-81-2).	For use only as an oil and water repellent and used at a level not to exceed 8 pounds per ton of the finished paper or paperboard when such paper or paperboard is used in contact with nonalcoholic foods under conditions of use E through H described in table 2 of paragraph (c) of this section.
dimethylacrylate copolymer (CAS Reg. No. 92265-81-1) containing 35 to 40 weight percent fluorine, produced by the copolymerization of ethanaminium, N,N,N-trimethyl-2-[(2-methyl-1-oxo-2-propenyl)-oxy]-, chloride; 2-propenoic acid, 2-methyl-, oxazanylmethyl ester; 2-propenoic acid, 2-ethoxyethyl ester; and 2-propenoic acid, 2[(heptadecafluoro-octylsulfonylethyl) methyl amino]ethyl ester.	For use only as an oil and water repellent at a level not to exceed 0.5 percent by weight of the finished paper and paperboard in contact with nonalcoholic foods under conditions of use C, D, E, F, G, or H described in table 2 of paragraph (c) of this section.
dimethylacrylate substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[(gamma-perfluoro-C ₈ -20-alkylthio) methyl]-1,3-propanediol, polyphosphoric acid and ammonium hydroxide.	For use only as an oil and water repellent at a level not to exceed 0.44 percent perfluoroalkyl actives by weight of the finished paper and paperboard in contact with non-alcoholic foods under condition of use H as described in table 2 of paragraph (c) of this section; and in contact with food of types III, IV-A, V, VII-A, and IX described in table 1 of paragraph (c) of this section under conditions of use C through G as described in table 2 of paragraph (c) of this section.
dimethylamine.	Complying with § 178.3700 of this chapter.
dimethyl asphalt, steam and vacuum refined to meet the following specifications: Softening point 88° C to 93° C, as determined by ASTM method D36-76, "Standard Test Method for Softening Point of Bitumen (Ring-and-Ball Apparatus);" Penetration at 25° C not to exceed 0.3 mm, as determined by ASTM method D5-73 (Reapproved 1978), "Standard Test Method for Penetration of Bituminous Materials," which are incorporated by reference (copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408); and maximum weight loss not to exceed 5% when distilled to 371° C, nor to exceed an additional 1.1% when further distilled between 371° C and thermal decomposition.	For use only as a component of internal sizing of paper and paperboard intended for use in contact only with raw fruits, raw vegetables, and dry food of the type identified under Type VIII of table 1 in paragraph (c) of this section, and provided that the asphalt is used at a level not to exceed 5% by weight of the finished dry paper and paperboard fibers.
dimethyl wax, synthetic.	Complying with § 178.3720 of this chapter.
dimethylamine.	For use only as antioxidant in dry rosin size.
dimethyl acid phosphate.	For use only as polymerization catalyst in melamine-formaldehyde modified alkyl coatings and limited to use at a level not to exceed 2% by weight of the coating solids.
dimethyl-N-naphthylamine.	For use only as antioxidant in dry rosin size and limited to use at a level not to exceed 0.4% by weight of the dry rosin size.

(d) *Limitations.* (1) The *n*-alkylglutarimide/acrylic copolymers in the finished form in which they shall contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature described in tables 1 and 2 of § 176.170(c) of this chapter, shall yield extractives not to exceed the limitations of § 177.1010(b) of this chapter, when prepared as strips, as described in § 177.1010(c)(2) of this chapter.

(2) The *n*-alkylglutarimide/acrylic copolymers shall not be used as polymer modifiers in vinyl chloride homo- or copolymers.

(e) *Conditions of use.* The *n*-alkylglutarimide/acrylic copolymers are used as articles or components of articles (other than articles composed of vinyl chloride homo- or copolymers) intended for use in contact with all foods except beverages containing more than 8 percent alcohol under conditions of use D, E, F, and G as described in table 2 of § 176.170(c) of this chapter.

[54 FR 20382, May 11, 1989, as amended at 58 FR 17098, Apr. 1, 1993]

§ 177.1200 Cellophane.

Cellophane may be safely used in packaging food in accordance with the following prescribed conditions:

(a) Cellophane consists of a base sheet made from regenerated cellulose to which have been added certain optional substances of a grade of purity suitable for use in food packaging constituents of the base sheet or coatings applied to impart desired technological properties.

(b) Subject to any limitations prescribed in this part, the optional substances used in the base sheet and coating may include:

(1) Substances generally recognized as safe in food.

(2) Substances for which prior approval or sanctions permit their use in cellophane, under conditions specified in such sanctions and substances listed in § 181.22 of this chapter.

(3) Substances that by any regulation promulgated under section 409 of the act may be safely used as components of cellophane.

(4) Substances named in this section and further identified as required.

(c) *List of substances:*

List of substances	Limitations (residue and limits of addition expressed as percentage by weight of finished packaging cellophane)
Acrylonitrile-butadiene copolymer resins	As the basic polymer.
Acrylonitrile-butadiene-styrene copolymer resins	Do.
Acrylonitrile-styrene copolymer resins	Do.
Acrylonitrile-vinyl chloride copolymer resins	Do.
N-Acyl sarcosines where the acyl group is lauroyl or stearoyl. ...	For use only as release agents in coatings at levels not to exceed a total of 0.3 percent by weight of the finished packaging cellophane.
Alkyl ketene dimers identified in § 176.120 of this chapter.	
Aluminum hydroxide.	
Aluminum silicate.	
Ammonium persulfate.	
Ammonium sulfate.	
Behenamide.	
Butadiene-styrene copolymer	As the basic polymer.
1,3-Butanediol.	
n-Butyl acetate	0.1 percent.
n-Butyl alcohol	Do.
Calcium ethyl acetoacetate.	
Calcium stearoyl-2-lactylate identified in § 172.844 of this chapter.	Not to exceed 0.5 percent weight of cellophane.
Carboxymethyl hydroxyethylcellulose polymer.	
Castor oil, hydrogenated.	
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol polyester.	As the basic polymer.
Castor oil phthalate, hydrogenated	Alone or in combination with other phthalates where phthalates do not exceed 5 percent.
Castor oil, sulfonated, sodium salt.	
Cellulose acetate butyrate.	
Cellulose acetate propionate.	
Cetyl alcohol.	
Clay, natural.	

List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
<p>Metamine-formaldehyde modified with one or more of the following: Butyl alcohol, diaminopropane, diethylenetriamine, ethyl alcohol, guanidine, imino-bis-butylamine, imino-bis-ethylamine, imino-bis-propylamine, methyl alcohol, polyamines made by reacting ethylenediamine or trimethylenediamine with dichloroethane or dichloropropane, sulfamic acid, tetraethylenepentamine, triethanolamine, triethylenetetramine.</p> <p>Methyl ethyl ketone</p> <p>Methyl hydrogen siloxane</p> <p>α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 α-methylstyrene to 3 vinyltoluene).</p> <p>Mineral oil, white.</p> <p>Naphthalenesulfonic acid-formaldehyde condensate, sodium salt.</p> <p>Nitrocellulose, 10.9 percent–12.2 percent nitrogen.</p> <p>Nylon resins complying with § 177.1500.</p> <p><i>n</i>-Octyl alcohol</p> <p>Olefin copolymers complying with § 177.1520.</p> <p>Oleic acid reacted with <i>N</i>-alkyl trimethylenediamine (alkyl C_{16} to C_{18}).</p> <p>Oleic acid, sulfonated, sodium salt.</p> <p>Oleyl palmitamide.</p> <p><i>N,N'</i>-Oleoyl-stearylethylenediamine (N-(2-stearoyl-aminoethyl)oleamide).</p> <p>Paraffin, synthetic, complying with § 175.250 of this chapter.</p> <p>Pentaerythritol tetrastearate</p> <p>Polyamide resins derived from dimerized vegetable oil acids (containing not more than 20 percent of monomer acids) and ethylenediamine as the basic resin.</p> <p>Polyamide resins having a maximum acid value of 5 and a maximum amine value of 8.5 derived from dimerized vegetable oil acids (containing not more than 10 percent monomer acids), ethylenediamine, and 4,4-bis(4-hydroxyphenyl)pentanoic acid (in an amount not to exceed 10 percent by weight of said polyamide resins).</p> <p>Polybutadiene resin (molecular weight range 2,000–10,200; bromine number range 210–320).</p> <p>Polycarbonate resins complying with § 177.1580.</p> <p>Polyester resin formed by the reaction of the methyl ester of rosin, phthalic anhydride, maleic anhydride, and ethylene glycol, such that the polyester resin has an acid number of 4 to 11, a drop-softening point of 70 °C–92 °C, and a color of K or paler.</p> <p>Polyethylene.</p> <p>Polyethylenearaminostearamide ethyl sulfate produced when stearic acid is made to react with equal parts of diethylenetriamine and triethylenetetramine and the reaction product is quaternized with diethyl sulfate.</p> <p>Polyethylene glycol (400) monolaurate.</p> <p>Polyethylene glycol (600) monolaurate.</p> <p>Polyethylene glycol (400) monooleate.</p> <p>Polyethylene glycol (600) monooleate.</p> <p>Polyethylene glycol (400) monostearate.</p> <p>Polyethylene glycol (600) monostearate.</p> <p>Polyethylene, oxidized: complying with the identity prescribed in § 177.1620(a).</p> <p>Polyethylenimine</p> <p>Polyisobutylene complying with § 177.1420.</p> <p>Polyoxypropylene-polyoxyethylene block polymers (molecular weight 1,900–9,000).</p> <p>Polypropylene complying with § 177.1520.</p> <p>Polystyrene</p> <p>Polyvinyl acetate</p> <p>Polyvinyl alcohol (minimum viscosity of 4 percent aqueous solution at 20 °C of 4 centipoises).</p> <p>Polyvinyl chloride</p>	<p>As the basic polymer, and used as a resin to anchor coatings to substrate.</p> <p>Residue limit 0.1 percent 0.1 percent as the basic polymer.</p> <p>0.1 percent, for use only as an emulsifier.</p> <p>For use only as a defoaming agent in the manufacture of cellophane base sheet.</p> <p>0.1 percent.</p> <p>For use only in cellophane coatings that contact food at temperatures not to exceed room temperature.</p> <p>As the basic resin, for use only in coatings that contact food at temperatures not to exceed room temperature provided that the concentration of the polyamide resins in the finished food-contact coating does not exceed 5 milligrams per square inch of food-contact surface.</p> <p>For use only as an adjuvant in vinylidene chloride copolymer coatings.</p> <p>0.1 percent.</p> <p>As the basic polymer, for use as a resin to anchor coatings to the substrate and for use as an impregnant in the food-contact surface of regenerated cellulose sheet in an amount not to exceed that required to improve heat-sealable bonds between coated and uncoated sides of cellophane.</p> <p>For use as an adjuvant employed during the processing of cellulose pulp used in the manufacture of cellophane base sheet.</p> <p>As the basic polymer. Do.</p> <p>As the basic polymer.</p>

Food and Drug Administration, HHS

(f) The microporous polymeric filters shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent potential microbial adulteration of the food.

(g) To assure safe use of the microporous polymeric filters, the label or labeling shall include adequate directions for a pre-use treatment, consisting of washing with a minimum of 2 gallons of potable water at a temperature of 180 °F for each square foot of filter, prior to the filter's first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 56 FR 42833, Aug. 30, 1991]

§ 177.2260 Filters, resin-bonded.

Resin-bonded filters may be safely used in producing, manufacturing, processing, and preparing food, subject to the provisions of this section.

(a) Resin-bonded filters are prepared from natural or synthetic fibers to which have been added substances required in their preparation and finishing, and which are bonded with resins prepared by condensation or polymerization of resin-forming materials, together with adjuvant substances required in their preparation, application, and curing.

(b) The quantity of any substance employed in the production of the resin-bonded filter does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of resin-bonded filters that is the subject of a regulation in parts 174, 175, 176, 177, 178 and 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of resin-bonded filters include the following, subject to any limitations provided:

LIST OF SUBSTANCES AND LIMITATIONS

(1) Fibers:

Cellulose pulp.

Cotton.

Nylon. (From nylon resins complying with the provisions of applicable regulations in subchapter B of this chapter.

Styethylene terephthalate complying in composition with the provisions of

§ 177.2260

§ 177.1630; for use in inline filtration only as provided for in paragraphs (e) and (f) of this section.

Rayon (viscose).

(2) Substances employed in fiber finishing:

BHT.

Butyl (or isobutyl) palmitate or stearate.

2,5-Di-tert-butylhydroquinone for use only in lubricant formulations for rayon fiber finishing and at a usage level not to exceed 0.1 percent by weight of the lubricant formulations.

Dimethylpolysiloxane.

4-Ethyl-4-hexadecyl morpholinium ethyl sulfate for use only as a lubricant in the manufacture of polyethylene terephthalate fibers specified in paragraph (d)(1) of this section at a level not to exceed 0.03 percent by weight of the finished fibers.

Fatty acid (C₁₀-C₁₈) diethanolamide condensates.

Fatty acids derived from animal or vegetable fats and oils, and salts of such acids, single or mixed, as follows:

Aluminum.

Ammonium.

Calcium.

Magnesium.

Potassium.

Sodium.

Triethanolamine.

Fatty acid (C₁₀-C₁₈) mono- and diesters of polyoxyethylene glycol (molecular weight 400-3,000).

Methyl esters of fatty acids (C₁₀-C₁₈).

Mineral oil.

Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740 (b) of this chapter.

Polyoxyethylene (4 mols) ethylenediamine monolauramide for use only in lubricant formulations for rayon fiber finishing and at a usage level not to exceed 10 percent by weight of the lubricant formulations.

Ricebran oil.

Titanium dioxide.

(3) Resins:

Acrylic polymers produced by polymerizing ethyl acrylate alone or with one or more of the monomers: Acrylic acid, acrylonitrile, N-methylolacrylamide, and styrene. The finished copolymers shall contain at least 70 weight percent of polymer units derived from ethyl acrylate, no more than 2 weight percent of total polymer units derived from acrylic acid, no more than 10 weight percent of total polymer units derived from acrylonitrile, no more than 2 weight percent of total polymer units derived from N-methylolacrylamide, and no more than 25 weight percent of total polymer units derived from styrene. For use only as provided in paragraph (m) of this section.

000071

000071

suitable support, its maximum weight shall be 512 milligrams per square inch. (4) A cross-linked high molecular weight polyamide reaction product of allyl-N-vinyl-N-methylamine (CAS Reg. No. 31245-56-4), N,N'-bis(3-aminopropyl)ethylenediamine (CAS Reg. No. 10583-26-5), 1,3-benzenedicarbonyl dichloride (CAS Reg. No. 99-63-8) and 1,3,5-benzenetricarbonyl trichloride (CAS Reg. No. 4422-95-1). The membrane is a food-contact surface. Its maximum weight is 20 milligrams per square inch (1.3 milligrams per square inch) a thin film composite on a suitable support.

5) A polyamide reaction product of 5-benzenetricarbonyl trichloride (CAS Reg. No. 4422-95-1) with diaminoethane (CAS Reg. No. 110-85-0) and 3). The membrane is the food-contact layer and may be applied as a film suitable support. Its maximum weight is 15 milligrams per square inch (1 milligram per square inch). (c) Optional adjuvant substances. The polymer identified in paragraph 3 of this section may contain optional adjuvant substances required in the production of such basic polymer. These optional adjuvant substances include substances permitted for use by regulations in parts 170 through 186 of this chapter, substances generally recognized as safe in food, and substances used in accordance with or sanction or approval. Supports. Suitable supports for reverse osmosis membranes are permitted for such use by regulation in parts 170 through 186 of this chapter, substances generally recognized as safe in food, and substances used in accordance with or approval.

Conditions of use (1) Reverse osmosis membranes described in paragraph (a)(1), (a)(2), (a)(3), and (a)(5) of this section may be used in contact with all types of liquid food at temperatures up to 80 °C (176 °F). Reverse osmosis membranes described in paragraph (a)(4) of this section may be used in contact with all types of liquid food, except food containing

(1) Elastomers.

taining more than 8 percent alcohol, at temperatures up to 80 °C (176 °F).

(3) Reverse osmosis membranes shall be maintained in a sanitary manner in accordance with current good manufacturing practice so as to prevent microbial adulteration of food.

(4) To assure their safe use, reverse osmosis membranes and their supports shall be thoroughly cleaned prior to their first use in accordance with current good manufacturing practice.

(49 FR 49448, Dec. 20, 1984, as amended at 52 FR 29668, Aug. 11, 1987; 53 FR 31835, Aug. 22, 1988; 53 FR 32215, Aug. 24, 1988; 55 FR 8138, Mar. 7, 1990; 59 FR 9926, Mar. 2, 1994)

§ 177.2600 Rubber articles intended for repeated use.

Rubber articles intended for repeated use may be safely used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The rubber articles are prepared from natural and/or synthetic polymers and adjuvant substances as described in paragraph (c) of this section.

(b) The quantity of any substance employed in the production of rubber articles intended for repeated use shall not exceed the amount reasonably required to accomplish the intended effect in the rubber article and shall not be intended to accomplish any effect in food.

(c) Substances employed in the preparation of rubber articles include the following, subject to any limitations prescribed:

- (1) Substances generally recognized as safe for use in food or food packaging
- (2) Substances used in accordance with the provisions of a prior sanction or approval
- (3) Substances that by regulation in parts 170 through 189 of this chapter may be safely used in rubber articles, subject to the provisions of such regulation.

(4) Substances identified in this paragraph (c)(4), provided that any substance that is the subject of a regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation

000073

Alkylated (C₆ and/or C₈) phenols.
BHT (butylated hydroxytoluene).
4-[[4,6-bis(octylthio)-s-triazin-2-yl]amino]-2,6-di-*tert*-butylphenol (CAS Reg. No. 991-84-4) for use only as a stabilizer at levels not to exceed 0.5 percent by weight of the finished rubber product.
Butylated reaction product of *p*-cresol and dicyclopentadiene as identified in § 178.2010(b) of this chapter.
Butylated, styrenated cresols identified in § 178.2010(b) of this chapter.
4,4'-Butyldienebis(6-*tert*-butyl-*m*-cresol).
N-Cyclohexyl-*N*'-phenylphenylenediamine.
p,p'-Diaminodiphenylmethane.
2,5-Di-*tert*-amylhydroquinone.
Diaryl-*p*-phenylenediamine, where the aryl group may be phenyl, tolyl, or xylyl.
2,6-Di-*tert*-butyl-*p*-phenylphenol.
1,2-Dihydro-2,2,4-trimethyl-6-dodecylquinoline.
1,2-Dihydro-2,2,4-trimethyl-6-ethoxyquinoline.
1,2-Dihydro-2,2,4-trimethyl-6-phenylquinoline.
4,4'-Dimethoxydiphenylamine.
4,6-Dimonyl-*o*-cresol.
N,N'-Dioctyl-*p*-phenylenediamine.
Diphenylamine-acetone-formaldehyde resin.
Diphenylamine-acetone-formaldehyde resin.
N,N'-Diphenylethylenediamine.
N,N'-Disalicylalpropylenediamine.
N,N'-Di-*o*-tolylethylenediamine.
Hydroquinone monobenzyl ether.
Isopropoxydiphenylamine.
N-Isopropyl-*N'*-phenyl-*p*-phenylenediamine.
2,2'-Methylenedi(6-*tert*-butyl-4-ethylphenol).
2,2'-Methylenedi(4-methyl-6-*tert*-butylphenol).
2,2'-Methylenedi(4-methyl-6-nonylphenol).
2,2'-Methylenedi(4-methyl-6-*tert*-octylphenol).
Monooctyl- and dioctyldiphenylamine.
N,N'-Di-*p*-naphthyl-*p*-phenylenediamine.
Phenyl-*α*-naphthylamine.
Phenyl-*β*-naphthylamine.
Phenyl-*β*-naphthylamine-acetone aromatic amine resin (average molecular weight 600; nitrogen content 5.3 percent).
o- and *p*-Phenylphenol. (mixture)
Polybutylated isopropylidenediphenol.
Sodium pentachlorophenate.
Styrenated cresols produced when 2 moles of styrene are made to react with 1 mole of a mixture of phenol and *o*-, *m*-, and *p*-cresols so that the final product has a Brookfield viscosity at 25 °C of 1400 to 1700 centipoises.
Styrenated phenol.
4,4'-Thiobis (6-*tert*-butyl-*m*-cresol).
Toluene-2,4-diamine.
N-*o*-Tolyl-*N'*-phenyl-*p*-phenylenediamine.
p,p'-Tolylisulfanilamide diphenylamine.
Tri(mixed mono- and dinonylphenyl) phosphite.
Tri(nonylphenyl) phosphite-formaldehyde resins produced when 1 mole of

000073

tri(nonylphenyl) phosphite is made to react with 1.4 moles of formaldehyde to produce when 1 mole of formaldehyde is made to react with 0.38 mole of formaldehyde and the reaction product is then further reacted with 0.33 mole of phosphorus trichloride. The finished resins have a minimum viscosity of 20,000 centipoises at 25 °C, as determined by LV-series Brookviscometer (or equivalent) using a spindle at 12 r.p.m., and have an average phosphorus content of 4.06 to 4.15 percent by weight.

(iv) Plasticizers (total not to exceed percent by weight of rubber product, less otherwise specified).

n-Amyl *n*-decyl phthalate.
Butylacetyl ricinoleate.
n-Butyl ester of tall oil fatty acids.
Butyl laurate.
Butyl oleate.
Butyl searate.
Calcium searate.
Castor oil.
Counarone-indene resins.
2,2'-Dibenzamido(diphenyl) disulfide.
Dibenzyl adipate.
Dibutoxyethoxyethyl adipate.
Dibutyl phthalate.
Dibutyl sebacate.
Didecyl adipate.
Didecyl phthalate.
Dioctyl adipate.
Dioctyl phthalate.
Dioctyl sebacate.
Dipentene resin.
Diphenyl ketone.
Fatty acids.
Fatty acids, hydrogenated.
Isooctyl ester of tall oil fatty acids.
Lanolin.
α-Methylstyrene-vinyltoluene copolymer resins (molar ratio 1 *α*-methylstyrene to 1 vinyltoluene).
Mineral oil: (1) In rubber articles complying with this section, not to exceed 30 percent by weight; (2) Alone or in combination with waxes, petroleum, total not to exceed 45 percent by weight of rubber articles; (3) Contain at least 20 percent by weight ethylene-propylene copolymer elastomer complying with paragraph (c)(4)(i) of this section, in contact with foods of Type II, III, IV, VI, VII, VIII, and IX identified in table 1 of § 176.170(c) of this chapter.
Montan wax.
n-Octyl *n*-decyl adipate.
n-Octyl *n*-decyl phthalate.
Petrolatum.
Petroleum hydrocarbon (cyclopentadiene type), hydrogenated.

420099

§ 177.2710

Zinc 4-tert-butylthiophenolate as peptizing agent.

(d) Rubber articles intended for use with dry food are so formulated and cured under conditions of good manufacturing practice as to be suitable for repeated use.

(e) Rubber articles intended for repeated use in contact with aqueous food shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with distilled water at reflux temperature, shall yield total extractives not to exceed 20 milligrams per square inch during the first 7 hours of extraction, nor to exceed 1 milligram per square inch during the succeeding 2 hours of extraction.

(f) Rubber articles intended for repeated use in contact with fatty foods shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with n-hexane at reflux temperature, shall yield total extractives not to exceed 175 milligrams per square inch during the first 7 hours of extraction, nor to exceed 4 milligrams per square inch during the succeeding 2 hours of extraction.

(g) In accordance with good manufacturing practice finished rubber articles intended for repeated use in contact with food shall be thoroughly cleaned prior to their first use in contact with food. The provisions of this section are not applicable to rubber nursing-bottle nipples.

(h) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

(42 FR 14572, Mar. 15, 1977)

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 177.2600, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 177.2710 Styrene-divinylbenzene resins, cross-linked.

Styrene-divinylbenzene cross-linked copolymer resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing,

preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions: (a) The resins are produced by the copolymerization of styrene with divinylbenzene.

(b) The resins meet the extractive limitations prescribed in this paragraph: (1) The resins to be tested are ground or cut into small particles that will pass through a U.S. standard sieve No. 3 and that will be held on a U.S. standard sieve No. 20.

(2) A 100-gram sample of the resins, when extracted with 100 milliliters of ethyl acetate at reflux temperature for 1 hour, yields total extractives not to exceed 1 percent by weight of the resins.

(c) In accordance with good manufacturing practice, finished articles containing the resins shall be thoroughly cleaned prior to their first use in contact with food.

§ 177.2800 Textiles and textile fibers.

Textiles and textile fibers may safely be used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The textiles and textile fibers prepared from one or more of the fibers identified in paragraph (d) of this section and from certain other substances required in the production of the textiles or textile fibers or additives to impart desired properties.

(b) The quantity of any additive substance employed in the production of textiles or textile fibers does not exceed the amount reasonably required to accomplish the intended physical, chemical, or technical effect or any limitation there provided.

(c) Any substance employed in the production of textiles or textile fibers that is the subject of a regulation in parts 174, 175, 176, 177, 178 and 179 of this chapter conforms with any limitation in such regulation.

(d) Substances employed in the production of or added to textiles and textile fibers may include:

- (1) Substances generally recognized as safe in food.
- (2) Substances subject to prior sanction or approval for use in textiles and textile fibers and used in accordance with such sanction or approval.
- (3) Substances generally recognized as safe for use in cotton and cotton fabrics used in dry-food packaging.
- (4) Substances that by regulation in this part may safely be used in the production of or as a component of textiles or textile fibers and subject to provisions of such regulation.
- (5) Substances identified in this paragraph (d)(5), subject to such limitations as are provided:

List of substances	Limitations
<p>Fibers:</p> <p>Cotton.</p> <p>Polyethylene terephthalate complying in composition with the provisions of § 177.1650(e)(4)(i).</p> <p>Adjuvant substances:</p> <p>Aluminum stearate.</p> <p>Borax.</p> <p>Diethyl-<i>N</i>-acetyl ricinoleate.</p> <p>Colorants used in accordance with § 177.3297 of this chapter.</p> <p>Di-<i>n</i>-butyl hydroquinone.</p> <p>Dimethylpolysiloxane.</p> <p>Ethylene diamine tetraacetic acid, sodium salt.</p> <p>2-Ethyl-4-hexadecyl morpholinium ethyl sulfate.</p> <p>Legend.</p> <p>fat, oil, fatty acids, and fatty alcohols derived from castor, coconut, cottonseed, fish, mustardseed, palm, peanut, rapeseed, ricin, soybean, sperm, and tall oils and tall oil acids, fatty acids, and fatty alcohols described in the preceding item reacted with one or more of the following substances:</p> <p><i>n</i>-Butyl and isobutyl alcohol</p> <p>Diethylene glycol</p> <p>Diethanolamine</p> <p>Glycerol</p> <p>Methylene glycol (2-methyl-2,4-pentanediol)</p> <p>Hydrogen</p> <p>Isopropyl alcohol</p> <p>Methyl alcohol</p> <p>Oxygen</p> <p>Polyethylene glycol (molecular weight 400-3,000)</p> <p>Potassium hydroxide</p> <p>Propylene glycol</p> <p>Sodium hydroxide</p> <p>Sulfuric acid</p> <p>Urethane</p> <p>Acetyl mono-12-hydroxystearate</p> <p>2-(2-Hydroxyethyl)-1-[2-(10-octadecanamide)ethyl]-2-hydroxyethyl sulfate</p> <p>Acetylene glycol (2-methyl-2,4-pentanediol)</p> <p>Methyl alcohol</p> <p>Isopropyl alcohol</p> <p>Acetone</p> <p>Ethyl ester of sulfated ricinoleic acid</p> <p>Mineral oil</p> <p>and diisopropylated <i>m</i>- and <i>p</i>-cresols (isothymol derivatives)</p> <p>Diethyl-<i>N</i>-acetyl-<i>N</i>-β-hydroxy-ethylenediamine</p> <p>Aluminum sulfonate</p> <p>in oil</p> <p>Acetone, hydrogenated, complying with the identity prescribed under 21 CFR 178.3740(b) of this chapter</p> <p>Acetylene, oxidized (air blown)</p> <p>Diethyl acetate</p> <p>Diethyl alcohol</p> <p>Aluminum soap of a saponified sulfated castor oil from bis(2,6-dimethylheptyl-4) sulfosuccinate</p>	<p>For use only in the manufacture of items for repeated use.</p> <p>For use as preservative only.</p> <p>For use only as a lubricant in the manufacture of polyethylene terephthalate fibers specified in paragraph (d)(5)(i) of this section at a level not to exceed 0.03 percent by weight of the finished fibers.</p> <p>For use as preservative only</p> <p>For use only at a level not to exceed 0.15 percent by weight of finished fibers</p>

derived petroleum wax is permitted in subchapter B of this chapter as a component of articles intended to contact food, provided that the synthetic petroleum wax meets the definition and specifications prescribed in §172.888 of this chapter.

§ 178.3725 Pigment dispersants.

Subject to the provisions of this regulation, the substances listed in this section may be safely used as pigment dispersants in food-contact materials.

Substances	Limitations
Phosphorylated tall oil fatty acids (CAS Reg. No. 68804-99-9), prepared by the reaction of dimethyl hydrogen phosphite with tall oil fatty acids.	For use only at levels not to exceed 1.0 percent by weight of the pigment. The pigmented polymeric films may contact food under conditions of use D, E, F, and G described in table 2 of § 176.170(c) of this chapter.

21 FR 43157, Aug. 21, 1998]

§ 178.3730 Piperonyl butoxide and pyrethrins as components of bags.

Piperonyl butoxide in combination with pyrethrins may be safely used for insect control on bags that are intended for use in contact with dried feed in compliance with §§561.310 and §61.340 of this chapter, or that are intended for use in contact with dried food in compliance with §§193.60 and 193.390 of this chapter.

§ 178.3740 Plasticizers in polymeric substances.

Subject to the provisions of this regulation, the substances listed in paragraph (b) of this section may be safely used as plasticizers in polymeric substances or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(b) List of substances:

Substances	Limitations
Diethylbenzyl phthalate	For use only: 1. As provided in §§ 175.105 and 178.180 of this chapter. 2. In polymeric substances used in food-contact articles complying with §§ 175.300, § 175.320, or § 176.170 of this chapter: Provided, That the butyl benzyl phthalate contains not more than 1 percent by weight of dibenzyl phthalate. 3. In polymeric substances used in other permitted food-contact articles: Provided, That the butyl benzyl phthalate contains not more than 1 percent by weight of dibenzyl phthalate; and Provided further, That the finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 175.300(d) of this chapter, shall yield not chloroform-soluble extractives not to exceed 0.5 mg. per square inch, as determined by the methods prescribed in § 175.300(e) of this chapter. For use at levels not exceeding 33 percent by weight of polyvinyl chloride homopolymer used in contact with food (except foods that contain more than 8 percent of alcohol) at temperatures not to exceed room temperature. The average thickness of such homopolymers in the form in which they contact food shall not exceed 0.004 inch.
1,3-Bis(4-phenyl glycidyl) acid polyester (1,700-2,200 molecular weight) terminated with a 16 percent by weight mixture of myristic, palmitic, and stearic acids	

000076

000076

.....
.. ..
.....
.....

Viscous Materials," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (f)(1) of this section.

(3) Acid number: Acid number shall be as determined by ASTM method D465-82, "Standard Test Methods for Acid Number of Rosin," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (f)(1) of this section.

(4) Viscosity: Viscosity in poises shall be as determined by ASTM method D1824-66 (Reapproved 1980), "Standard Test Method for Apparent Viscosity of Plastics and Organosols at Low Shear Rates by Brookfield Viscometer," and in Saybolt seconds by ASTM method D88-81, "Standard Test Method for Saybolt Viscosity," which are incorporated by reference. The availability of this incorporation by reference is given in paragraph (f)(1) of this section.

(5) Softening point: Softening point shall be as determined by ASTM method E28-67, "Standard Test Method for Softening Point by Ring and Ball Apparatus" (Reapproved 1977), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race St., Philadelphia, PA 19103, or the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC 20408.

(6) Analytical methods for determining drop-softening point, saponification number, and any other specifications not listed under paragraphs (f)(1) through (5) of this section, titled: (i) "Determination of Abietic Acid and Dehydroabietic Acid in Rosins"; (ii) "Determination of Softening Point of Solid Resins"; (iii) "Determination of Saponification Number of Rosin Esters," and (iv) "Determination of Phenolic Modification of Rosin Derivatives," which are incorporated by reference.

ence. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC 20408.

[2 FR 14699, Mar. 15, 1977, as amended at 47 FR 11899, Mar. 19, 1982; 49 FR 10113, Mar. 18, 1984; 54 FR 24899, June 12, 1989]

§ 178.3900 Sodium pentachlorophenate.

Sodium pentachlorophenate may be safely used as a preservative for ammonium alginate employed as a processing aid in the manufacture of polyvinyl chloride emulsion polymers intended for use as articles or components of articles that contact food at temperatures not to exceed room temperature. The quantity of sodium pentachlorophenate used shall not exceed 0.5 percent by weight of ammonium alginate solids.

§ 178.3910 Surface lubricants used in the manufacture of metallic articles.

The substances listed in this section may be safely used in surface lubricants employed in the manufacture of metallic articles that contact food, subject to the provisions of this section.

- (a) The following substances may be used in surface lubricants used in the rolling of metallic foil or sheet stock provided that total residual lubricant remaining on the metallic article in the form in which it contacts food does not exceed 0.015 milligram per square inch of metallic food-contact surface:
- (1) Substances identified in paragraphs (b)(1) and (2) of this section.
 - (2) Substances identified in this paragraph.

List of substances	Limitations
<p>α-Butyl-D-hydroxypropyl (acrylate)-poly (acrylate) (CAS Reg. No. 9038-95-3) produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol and having a minimum molecular weight of 1,000.</p> <p>α-Butyl-D-hydroxypropyl-D</p> <p>α-butyl-D-hydroxypropyl-D</p>	<p>For use at levels not to exceed 20 percent by weight of the finished lubricant formulation.</p>

List of substances	Limitations
<p>Synthetic primary alcohol mixture of straight- and branched-chain alcohols that contain at least 99 pct primary alcohols consisting of the following: not less than 70 percent normal alcohols; not less than 93 pct C₁₂-C₁₈ alcohols; not more than 5 pct C₁₂-C₁₈ alcohols; and not more than 2.5 pct alpha-omega, C₁₂-C₁₈ diols. The alcohols are prepared from linear olefins from a purified kerosene fraction, carbon monoxide and hydrogen using a modified oxo process, such that the finished primary alcohol mixture meets the following specifications:</p> <p>Molecular weight 19445; hydroxy number, 283-296; Tallow, sulfonated.</p> <p>Triethanolamine.</p>	<p>For use only at a level not to exceed 8 pct by weight in lubricant formulation.</p>

300079

(3) Mineral oil conforming to the identity prescribed in §178.3620(c).

(4) Light petroleum hydrocarbons identified in paragraph (a)(4) (1) of this section: *Provided*, That the total residual lubricant on the metallic article in the form in which it contacts food meets the ultraviolet absorbance limits prescribed in paragraph (a) (4) (ii) of this section as determined by the analytical method described in paragraph (a) (4) (iii) of this section.

(i) Light petroleum hydrocarbons are derived by distillation from virgin petroleum stocks or are synthesized from aromatic, isoparaffinic, naphthenic, or aromatic in nature, and meet the following specifications:

(a) Initial boiling point is 24 °C minimum and final boiling point is 288 °C maximum, as determined by ASTM method D86-82, "Standard Method for Distillation of Petroleum Products," which is incorporated by reference. Copies may be obtained by reference, American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20540.

(b) Nonvolatile residue is 0.005 gram per 100 milliliters, maximum, as determined by ASTM method D381-80, "Standard Test Method for Existing Gum in Fuels by Jet Evaporation," when the final boiling point is 121 °C or above and by ASTM method D133-78, "Standard Test Method for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products," when the final boiling point is below 121 °C. These ASTM methods are incorporated by reference. The

availability of these incorporation reference is given in paragraph (a)(4)(i)(a) of this section.

(c) Saybolt color 20 minimum as determined by ASTM method D156 Color of Petroleum Products (Saybolt Chromometer Method), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(4)(i)(a) of this section.

(d) Aromatic component content shall not exceed 32 percent.

(e) Conforms with ultraviolet absorbance limits prescribed in §178.3620(c) determined by the analytical method described therein.

(ii) Ultraviolet absorbance limits: residual lubricants are as follows:

Wavelength (nm)	Maximum absorbance per centimeter or optical density
280-289	0
290-299	0
300-359	0
360-400	0

(iii) The analytical method for determining ultraviolet absorbance limits on residual lubricants is as follows:

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent, residues, etc. Examine all glassware including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane

Food and Drug Administration, RMS

(e) The label and labeling of food a single serving of which would be expected to exceed 15 grams of the additive shall bear the statement: "Sensitive individuals may experience a laxative effect from excessive consumption of this product".

[46 FR 30081, June 5, 1981, as amended at 59 FR 37421, July 22, 1994; 60 FR 54425, Oct. 24, 1995; 61 FR 14480, Apr. 2, 1996; 62 FR 30985, June 6, 1997]

§ 172.842 Sorbitan monostearate.

The food additive sorbitan monostearate, which is a mixture of partial stearic and palmitic acid esters of sorbitol anhydrides, may be safely used in or on food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield essentially a mixture of esters.

(b) The food additive meets the following specifications:

Saponification number, 147-157

Acid number, 5-10

Hydroxyl number, 235-260

(c) It is used or intended for use, alone or in combination with polysorbate 60 as follows:

(1) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

(i) Polysorbate 60;

(ii) Polysorbate 65;

(iii) Polysorbate 80;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping, except that a combination of the additive with polysorbate 60 may be used in excess of 0.4 percent. *Provided*, That the amount of the additive does not exceed 0.27 percent and the amount of polysorbate 60 does not exceed 0.77 percent of the weight of the finished whipped edible oil topping.

(2) As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:

(i) Polysorbate 65.

(ii) Polysorbate 60.

When used alone, the maximum amount of sorbitan monostearate shall not exceed 0.61 percent of the cake or

cake mix, on a dry-weight basis. When used with polysorbate 65 and/or polysorbate 60, it shall not exceed 0.61 percent, nor shall the polysorbate 65 exceed 0.32 percent or the polysorbate 60 exceed 0.46 percent, and no combination of the emulsifiers shall exceed 0.66 percent of the weight of the cake or cake mix, calculated on a dry-weight basis.

(3) As an emulsifier, alone or in combination with polysorbate 60 in non-standardized confectionery coatings and standardized cacao products specified in §§ 163.123, 163.130, 163.135, 163.140, 163.145, and 163.150 of this chapter, as follows:

(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(ii) It is used with polysorbate 60 in any combination of up to 1 percent sorbitan monostearate and up to 0.5 percent polysorbate 60 provided that the total combination does not exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(4) As an emulsifier in cake icings and cake fillings, with or without one or a combination of the following:

(i) Polysorbate 65.

(ii) Polysorbate 60.

When used alone, the maximum amount of sorbitan monostearate shall not exceed 0.7 percent of the weight of the cake icing or cake filling. When used with polysorbate 65 and/or polysorbate 60, it shall not exceed 0.7 percent, nor shall the polysorbate 65 exceed 0.32 percent or the polysorbate 60 exceed 0.46 percent, and no combination of these emulsifiers shall exceed 1 percent of the weight of the cake icing or cake filling.

(5) As an emulsifier in solid-state, edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, with or without one or a combination of the following:

(i) Polysorbate 60

(ii) Polysorbate 65.

The maximum amount of the additive or additives shall not exceed 0.4 percent by weight of the finished edible vegetable fat-water emulsion.

(6) It is used alone as a rehydration aid in the production of active dry yeast in an amount not to exceed 1 percent by weight of the dry yeast.

(7) As an emulsifier, alone or in combination with polysorbate 60, in the minimum quantity required to accomplish the intended effect, in formulations of white mineral oil conforming with §172.878 and/or petroleum wax conforming with §172.886 for use as protective coatings on raw fruits and vegetables.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 2871, Jan. 20, 1978]

§ 172.844 Calcium stearoyl-2-lactylate.

The food additive calcium stearoyl-2-lactylate may be safely used in or on food in accordance with the following prescribed conditions:

(a) The additive, which is a mixture of calcium salts of stearoyl lactic acids and minor proportions of other calcium salts of related acids, is manufactured by the reaction of stearic acid and lactic acid and conversion to the calcium salts.

(b) The additive meets the following specifications:

Acid number, 50-86.

Calcium content, 4.2-5.2 percent.

Lactic acid content, 32-38 percent.

Ester number, 125-164.

(c) It is used or intended for use as follows:

(1) As a dough conditioner in yeast-leavened bakery products and prepared mixes for yeast-leavened bakery products in an amount not to exceed 0.5 part for each 100 parts by weight of flour used.

(2) As a whipping agent in:

(i) Liquid and frozen egg white at a level not to exceed 0.05 percent.

(ii) Dried egg white at a level not to exceed 0.5 percent.

(iii) Whipped vegetable oil topping at a level not to exceed 0.3 percent of the weight of the finished whipped vegetable oil topping.

(3) As a conditioning agent in dehydrated potatoes in an amount not to exceed 0.5 percent by weight thereof.

(d) To assure safe use of the additive, in addition to the other information required by the act, the following:

(1) The label of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling of the food additive shall also bear adequate directions of use to provide a finished food that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.846 Sodium stearoyl lactylate.

The food additive sodium stearoyl lactylate (CAS Reg. No. 25-383-997) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive, which is a mixture of sodium salts of stearoyl lactic acids and minor proportions of sodium salts of related acids, is manufactured by the reaction of stearic acid and lactic acid and conversion to the sodium salts.

(b) The additive meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 300-301, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW, Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC 20540.

(c) It is used or intended for use as follows when standards of identity established under section 401 of the Act do not preclude such use:

(1) As a dough strengthener, emulsifier, or processing aid in baked products, pancakes, and waffles, in an amount not to exceed 0.5 part for each 100 parts by weight of flour used.

APPENDIX VIII**MINERAL OIL**

CASRN: 8012-95-1

*For other data, click on the Table of Contents***Laboratory Methods:****Analytic Laboratory Methods:****COLUMN CHROMATOGRAPHY OF MINERAL OIL IN BAKED PRODUCTS.**

[Association of Official Analytical Chemists. Official Methods of Analysis. 10th ed. and supplements. Washington, DC: Association of Official Analytical Chemists, 1965. New editions through 13th ed. plus supplements, 1982., p. 13/226 14.117]

****PEER REVIEWED******DETERMINATION OF MINERAL OIL IN FATS.**

[Association of Official Analytical Chemists. Official Methods of Analysis. 10th ed. and supplements. Washington, DC: Association of Official Analytical Chemists, 1965. New editions through 13th ed. plus supplements, 1982., p. 13/458 28.122]

****PEER REVIEWED******USE OF 1,1,2-TRICHLOROTRIFLUOROETHANE FOR THE QUANTITATIVE DETERMINATION OF MINERAL OIL AIR SAMPLE BY UV ABSORPTION.**

[WALDRON T; ANN OCCUP HYG 21 (2): 229-32 (1978)] ****PEER REVIEWED****

TECHNIQUES FOR ANALYZING AQUATIC MINERAL OIL POLLUTION ARE PRESENTED.

[CARLBERG SR; FAO FISH TECH PAP 137: 85-97 (1975)] ****PEER REVIEWED****

000082

Pages 000083 - 000084 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Page 000085 has been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Page 000086 has been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Pages 000087 - 000088 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Pages 000089 - 000090 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Page 000091 has been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Page 000092 has been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

MINERAL OIL

CASRN: 8012-95-1

*For other data, click on the Table of Contents***Human Health Effects:****Human Toxicity Excerpts:**

IF IT GAINS ACCESS TO LUNGS MINERAL OIL PRODUCES LIPID PNEUMONITIS. ALTHOUGH MORE FREQUENTLY OBSERVED WHEN OIL WAS USED AS VEHICLE FOR APPLICATION OF DRUGS TO NASAL MUCOUS MEMBRANES, LIPID PNEUMONITIS CAN ALSO OCCUR FOLLOWING ORAL INGESTION OF OIL, PARTICULARLY IF...TAKEN @ BEDTIME. ... LEAKAGE OF OIL PAST ANAL SPHINCTER IS AN ANNOYING SIDE EFFECT AND AN OCCASIONAL CAUSE OF PRURITUS ANI. IT IS ALSO CLAIMED THAT OIL INTERFERES WITH HEALING OF POSTOPERATIVE WOUNDS IN ANORECTAL REGION AND THAT CONTINUOUS PRESENCE OF OIL IN RECTUM DISTURBS NORMAL DEFECATORY REFLEXES.

[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 1009]**PEER REVIEWED**

MINERAL OIL ACTS AS A LIPID SOLVENT; ADMIN WITH MEALS, IT MAY INTERFERE WITH ABSORPTION OF ESSENTIAL FAT-SOLUBLE SUBSTANCES. REGULAR INGESTION OF MINERAL OIL DURING PREGNANCY MAY REDUCE ABSORPTION OF VITAMIN K & PRODUCE HYPOPROTHROMBINEMIA. /IN INTESTINAL TRACT/...ELICITS TYPICAL FOREIGN-BODY REACTION IN INTESTINAL MUCOSA, MESENTERIC LYMPH NODES, LIVER, AND SPLEEN. ALTHOUGH NO PHYSIOLOGICAL DISTURBANCES HAVE BEEN RELATED TO PRESENCE OF OIL AT THESE SITES, IT MUST BE QUESTIONED WHETHER /OIL/...CAN BE USED SAFELY OVER LONG PERIODS OF TIME.

[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 1009]**PEER REVIEWED**

...IF TAKEN CONTINUOUSLY IN LARGE AMT IT MAY IMPAIR APPETITE...

[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 746]**PEER REVIEWED**

/IN NASAL DROPS & SPRAYS/...OIL GRAVITATES TO LOWER LOBES OF LUNGS, WHERE IT SETS UP A GRANULOMATOUS REACTION, FOLLOWED BY MARKED FIBROSIS & ENCYSTMENT. DAILY ORAL DOSES OF 30-90 ML FOR MANY MONTHS HAS PRODUCED THE SAME EFFECT. THE FATALITY OF THIS COMPLICATION IS HIGH.

[Thienes, C., and T.J. Haley. Clinical Toxicology. 5th ed. Philadelphia: Lea and Febiger, 1972. 192]**PEER REVIEWED**

IN AN INSTANCE OF POSSIBLE EMBOLISM FROM AN OIL INJECTION, ONE PATIENT HAD RAPID LOSS OF VISION, SEVERE HEADACHE, CONVULSIONS, & COMA IMMEDIATELY AFTER INJECTION OF...MINERAL OIL PREPN, GRANUGENOL, INTO PLEURAL CAVITY IN TREATMENT OF EMPYEMA. RECOVERING GRADUALLY...WITHIN 3 WK VISION HAD RETURNED ESSENTIALLY TO NORMAL.

[Grant, W. M. Toxicology of the Eye. 2nd ed. Springfield, Illinois: Charles C. Thomas, 1974. 803]**PEER REVIEWED**

LIQ PETROLATUM...CAN BE APPLIED TO HUMAN EYES WITHOUT CAUSING DISCOMFORT OR SIGNS OF IRRITATION.

[Grant, W. M. Toxicology of the Eye. 2nd ed. Springfield, Illinois: Charles C. Thomas, 1974. 801]**PEER REVIEWED**

MASSIVE VISCERAL LIPID DEPOSITION FOLLOWING THE PROLONGED ORAL USE OF MINERAL OIL IS REPORTED.

[NOCHOMOVITZ LE, UYS CJ; S AFR J LAB CLIN MED 20 (2): 1226 (1974)]**PEER REVIEWED**

/Mineral oil/ occasionally may cause miliaria and folliculitis.

[American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994. 1221]**PEER REVIEWED**

Foreign-body granulomas or paraffinomas in the liver, spleen, or mesenteric lymph nodes have been reported following systemic absorption of mineral oil.

[American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994. 952]**PEER REVIEWED**

Hypoprothrombinemia and hemorrhagic disease of the newborn has occurred when mineral oil was chronically administered orally to pregnant women.

[McEvoy, G.K. (ed.). American Hospital Formulary Service--Drug Information 94. Bethesda, MD: American Society of Hospital Pharmacists, Inc. 1994 (Plus Supplements). 1885]**PEER REVIEWED**

The major findings in a laxative abuse patient include chronic diarrhea, vomiting, abdominal pain, lassitude, thirst, weakness (15%), edema, bone pain resulting from osteomalacia, and weight loss. Findings may disclose a protein-losing enteropathy, steatorrhea, pathologic colon changes associated with featureless radiologic findings (10%-30%), acid-base abnormalities (20%-25%), and hypokalemia (20%-25%). /Laxative abuse/

[Ellenhorn, M.J. and D.G. Barceloux. Medical Toxicology - Diagnosis and Treatment of Human Poisoning. New York, NY: Elsevier Science Publishing Co., Inc. 1988. 542]**PEER REVIEWED**

The NIOSH investigated complaints from workers in plants where oil mist was known to occur. None of the studies identified evidence of skin or respiratory tract irritation from exposures to oil mists that were at levels below the 5 mg/cu m TLV-TWA. /Oil mist, mineral/

[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1146]**PEER REVIEWED**

In a Norwegian cross-sectional matched pair study, 5 cable plant workers exposed to mists and vapors of mineral oil and kerosene for 5 to 35 years were investigated. An increased prevalence of slight basal lung fibrosis was found in the chest films of the exposed workers. Although oil mist levels were reported in the range of 0.15 to 0.30 mg/cu m, ... /it was/ suggested that the sampling methodology underestimated the actual exposure. Furthermore, the contribution of substantial short-term vapor exposures (reported up to 4000 mg/cu m) to lung fibrosis is uncertain. /Oil mist, mineral/

[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1146]**PEER REVIEWED**

Lipoid pneumopnia has been reported following heavy exposure to oil mist in the absence of adequate

ventilation. /Oil mist, mineral/

[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1146]**PEER REVIEWED**

In a survey of cause-specific mortality rates of 5189 workers exposed to oil mist and employed for at least 1 year on metal machinery in a heavy industrial plant, no excess of digestive tract or respiratory tract cancers was reported or dose-response relationship shown. /Oil mist, mineral/

[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1146]**PEER REVIEWED**

Injection of liquid petrolatum into the lacrimal system of patients with chronic epiphora produced a mass in the lower lid with inflammation in one, and infiltration of the orbit with interference in motion of the eye in another, both requiring surgery for relief.

[Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986. 715]**PEER REVIEWED**

Up to 1978, more than 400 cases of lipid pneumonia were reported in the literature to be related to oral administration of mineral oil, to oil-based nose drops or to intralaryngeal injection of medicinal oil.

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work).,p. V33 135 (1984)]**PEER REVIEWED**

Peritoneal lipid granuloma was observed in an individual who received mineral oil in the chest for a permanent collapse of the lung (oleothorax); it was noted that the substance had been introduced inadvertently into the abdominal cavity.

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work).,p. V33 135 (1984)]**PEER REVIEWED**

Lipid granulomas of the lung are localized lipid pneumonia, usually found in adults as a result of habitual use of large amounts of mineral oil (liquid petrolatum) by nasal, oral or pharyngeal administration for prolonged periods of time.

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work).,p. V33 135 (1984)]**PEER REVIEWED**

Drug Warnings:

...CAN CAUSE VARIETY OF UNTOWARD EFFECTS, & ITS USE AS A LAXATIVE REQUIRES APPRECIATION OF ITS POTENTIAL HAZARDS... HABITUAL USE OF MINERAL OIL MUST BE AVOIDED. ... INDISCRIMINATE USE...BY ELDERLY, DEBILITATED, OR DYSPHAGIC INDIVIDUALS SHOULD BE DISCOURAGED.

[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 1009]**PEER REVIEWED**

ORAL USE FOR MORE THAN TWO WEEKS COATS THE MUCOSA OF THE SMALL INTESTINE AND REDUCES THE ADSORPTION OF VITAMINS, ESPECIALLY THE FAT-SOLUBLE VITAMINS (A, D, E, AND K). THE PATIENT SHOULD BE WARNED THAT LIPID PNEUMONIA MAY OCCUR IF MINERAL OIL IS ASPIRATED AND THAT UNTOWARD

EFFECTS, SUCH AS HEPATIC INFILTRATION, CAN RESULT FROM ITS ABSORPTION. BECAUSE OF THE THEORETICAL POSSIBILITY THAT CONCURRENT USE OF THE VARIOUS DETERGENT DOCUSATE SALTS MAY FURTHER ENHANCE THE ABSORPTION OF MINERAL OIL, THEIR CONCOMITANT ADMINISTRATION IS NOT RECOMMENDED.

[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 1307]**PEER REVIEWED**

MINERAL OIL STILL PRESCRIBED BY SOME SURGEONS AFTER ANORECTAL SURGERY DESPITE THE FACT THAT IT SOMETIMES CAUSES PRURITUS ANI, & LACERATION OF THE AREA FROM SCRATCHING OR RUBBING INTERFERES WITH HEALING.

[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 1308]**PEER REVIEWED**

In recent years, the oral use of mineral oil has not been advocated because of the possibility of interference with the absorption of fat-soluble vitamins and the danger of pulmonary aspiration. The dose required for the former effect exceeds that normally used in clinical practice. ... Oral mineral oil should not be given to patients with swallowing abnormalities.

[American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994. 951]**PEER REVIEWED**

Oral mineral oil is not recommended for bedridden elderly patients since they are more prone to aspiration of oil droplets, which may produce lipid pneumonia.

[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1705]**PEER REVIEWED**

Oral mineral oil is not recommended for children up to 6 years of age since patients in this age group are more prone to aspiration of oil droplets, which may produce lipid pneumonia.

[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1705]**PEER REVIEWED**

... The use of olive or mineral oil /for treating petroleum distillate poisoning is controversial. The oil is used to/ increase the viscosity, thereby decreasing the chance of aspiration if vomiting occurs after the initial ingestion. Such oil also acts as a cathartic to hasten the petroleum distillate from the gastrointestinal tract. however, if aspirated, the oil can cause lipid pneumonia. A 6 year retrospective study showed as increased incidence of pneumonia in children who were given oil, therefore the use of oils should be avoided.

[Haddad, L.M., Clinical Management of Poisoning and Drug Overdose. 2nd ed. Philadelphia, PA: W.B. Saunders Co., 1990. 1184]**PEER REVIEWED**

Populations at Special Risk:

Oral mineral oil should not be given to patients with swallowing abnormalities.

[American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994. 951]**PEER REVIEWED**

Oral administration of mineral oil is contraindicated in children younger than 6 years of age; in bedridden, geriatric, debilitated, or pregnant patients; and in patients with esophageal or gastric retention, dysphagia, or hiatal hernia.

[McEvoy, G.K. (ed.). American Hospital Formulary Service--Drug Information 94. Bethesda, MD: American Society of Hospital Pharmacists, Inc. 1994 (Plus Supplements). 1885]**PEER REVIEWED**

Minimum Fatal Dose Level:

1= PRACTICALLY NON-TOXIC: PROBABLE ORAL LETHAL DOSE (HUMAN) ABOVE 15 G/KG, MORE THAN 1 QUART (2.2 LB) FOR 70 KG PERSON (150 LB).

[Gosselin, R.E., R.P. Smith, H.C. Hodge. Clinical Toxicology of Commercial Products. 5th ed. Baltimore: Williams and Wilkins, 1984.,p. II-156]**PEER REVIEWED**

BLANK PAGE INSERTED FOR CORRECT PAGINATION

000098



Computer Technology Services, Inc.

MINERAL OIL

CASRN: 8012-95-1

For other data, click on the Table of Contents

Emergency Medical Treatment:

Emergency Medical Treatment:

EMT Copyright Disclaimer:

Portions of the POISINDEX(R) database are provided here for general reference. THE COMPLETE POISINDEX(R) DATABASE, AVAILABLE FROM MICROMEDEX, SHOULD BE CONSULTED FOR ASSISTANCE IN THE DIAGNOSIS OR TREATMENT OF SPECIFIC CASES. Copyright 1974-1998 Micromedex, Inc. Denver, Colorado. All Rights Reserved. Any duplication, replication or redistribution of all or part of the POISINDEX(R) database is a violation of Micromedex' copyrights and is strictly prohibited.

The following Overview, *** LAXATIVES-EMOLLIENT ***, is relevant for this HSDB record chemical.

Life Support:

- o This overview assumes that basic life support measures have been instituted.

Clinical Effects:

SUMMARY OF EXPOSURE

0.2.1.1 ACUTE EXPOSURE

- o Toxicity following acute ingestion of excessive amounts of these laxatives is generally minimal and limited to the gastrointestinal tract.
- 1. Onset of symptoms may be delayed for up to 1 to 3 days. Nausea, vomiting, and diarrhea may be noted. Aspiration of mineral oil may result in pneumonitis.
- 2. SPECIFIC REPRESENTATIVES of the class of emollient laxatives include; mineral oil, dioctyl calcium sulfosuccinate, dioctyl sodium sulfosuccinate, dioctyl potassium sulfosuccinate.

RESPIRATORY

0.2.6.1 ACUTE EXPOSURE

- o Mineral oil, if aspirated, may result in pneumonitis.

GASTROINTESTINAL

0.2.8.1 ACUTE EXPOSURE

- o Nausea, vomiting, diarrhea, foreign body reaction, intestinal obstruction, melanosis coli, cathartic colon, and fecal leakage may be noted.

Laboratory:

- o Plasma levels of these agents are not clinically useful.
- o Obtain baseline CBC, serum electrolytes, and pertinent roentgenographic studies in symptomatic patients.

Treatment Overview:

000099

SUMMARY EXPOSURE

- o Do not induce emesis unless coingestants of greater clinical concern are present. Use activated charcoal only in large ingestions or with suspected coingestants. Do not use cathartics.
- o Correct fluid and electrolyte imbalance.
- o Provide supportive respiratory care for aspiration lipoid pneumonitis.

ORAL EXPOSURE

- o Due to aspiration hazard and generally low toxicity of these compounds, emesis is not recommended unless a serious coingestant or other clinical concern exists.
- o Due to potential for inducing vomiting, use activated charcoal only in very large ingestions or with a serious coingestant or other clinical concern.
- o DO NOT ADMINISTER A CATHARTIC.
- o EXCESSIVE DIARRHEA should be treated with high fluid intake (Pedialyte or Gatorade) and monitoring of fluid and electrolyte status. Restrict solid food intake until diarrhea resolves.

Range of Toxicity:

- o Signs and symptoms of toxicity are referable to the gastrointestinal tract.
- o Severity of intoxication should be based on clinical findings. Dehydration and electrolyte imbalance are the most serious manifestations of toxicity.

[Rumack BH: POISINDEX(R) Information System. Micromedex, Inc., Englewood, CO, 2000; CCIS Volume 104, edition exp May, 2000. Hall AH & Rumack BH (Eds):TOMES(R) Information System. Micromedex, Inc., Englewood, CO, 2000; CCIS Volume 104, edition exp May, 2000.] **PEER REVIEWED**

Antidote and Emergency Treatment:

... MINERAL OIL /IS/ ... CONSIDERED TO BE RELATIVELY NONTOXIC & /DOES NOT/ ... REQUIRE /VOMITING/.

[Amdur, M.O., J. Doull, C.D. Klaasen (eds). Casarett and Doull's Toxicology. 4th ed. New York, NY: Pergamon Press, 1991. 935]**PEER REVIEWED**

IN A CASE OF CHRONIC MINERAL OIL PNEUMONIA (CAUSED BY LAXATIVE ADMIN), EXPTL TREATMENT WITH SCHEDULED COUGHING SPELLS & EXPECTORATION CAN IMPROVE PATIENT PROGNOSIS.

[HECKERS H ET AL; LUNG 155 (2): 101-10 (1978)]**PEER REVIEWED**

000100

MINERAL OIL

CASRN: 8012-95-1

For other data, click on the Table of Contents

Animal Toxicity Studies:

Non-Human Toxicity Excerpts:

/PARENTERALLY IN VACCINES/...GRANULOMATOUS REACTIONS AT INJECTION SITES ARE NOT UNCOMMON. SIMILAR REACTIONS CAN OCCUR FROM ITS USE AS A LUBRICANT ON EXPLORATORY INSTRUMENTS...

[Rossoff, I.S. Handbook of Veterinary Drugs. New York: Springer Publishing Company, 1974. 367]**PEER REVIEWED**

REGULAR ORAL USE MAY INTERFERE WITH ABSORPTION OF FAT SOLUBLE VITAMINS...150 ML DAILY TO COWS CAUSED MARKED DECR IN CAROTENE & TOCOPHEROL BLOOD LEVELS AS WELL AS ACCELERATING POSTPARTURIENT DECR IN CAROTENE, VITAMIN A ESTER, TOCOPHEROL, & XANTHOPHYLL IN MILK...IT MAY ALSO PREVENT GROWTH OF INTESTINAL MICROORGANISMS AS FEEDING IT TO RATS PRODUCES VITAMIN K DEFICIENCY.

[Rossoff, I.S. Handbook of Veterinary Drugs. New York: Springer Publishing Company, 1974. 366]**PEER REVIEWED**

INJECTION OF MINERAL OIL...INTO ANTERIOR CHAMBER OF RABBITS, REPLACING THE AQUEOUS HUMOR, HAS BEEN USED TO OBSTRUCT AQUEOUS OUTFLOW & TO INDUCE GLAUCOMA EXPTL. THIS PRESUMABLY IS A MECHANICAL EFFECT RATHER THAN TOXIC REACTION.

[Grant, W. M. Toxicology of the Eye. 2nd ed. Springfield, Illinois: Charles C. Thomas, 1974. 803]**PEER REVIEWED**

RABBITS INJECTED IP WITH 30 CC PARAFFIN OIL SCORED AN UNUSUALLY HIGH FREQUENCY (2.8%) OF WELL-SPREAD METAPHASES IN THE PERITONEAL CAVITY.

[PLASSARA M ET AL; RES J RETICULOENDOTHEL SOC 12: 340-2 (1972)]**PEER REVIEWED**

PLASMACYTOMAS WERE FOUND IN 58% OF 373 BALB/CANN (C) MICE GIVEN 3 0.5-ML DOSES OF MINERAL OIL.

[POTTER M ET AL; J NATL CANCER INST 54 (6): 1413-8 (1975)]**PEER REVIEWED**

DOGS, RATS, MICE, & GERBILS WERE EXPOSED FOR 6 HR, 5 DAYS/WK UP TO 2 YR TO AN ATMOSPHERE CONTAINING A MINERAL OIL-BASE MIST @ CONCN OF 5 & 100 MG/CU M. ONLY @ 100 MG/CU M IN DOGS & RATS, BUT NOT IN MICE & GERBILS, DID MICROGRANULOMAS DEVELOP.

[STULA EF, KWON BK; AM IND HYG ASSOC J 39 (5): 393-9 (1978)]**PEER REVIEWED**

Groups of 25 9 day old chicken embryos were exposed to 10 or 20 ul pharmaceutical mineral oil on the eggshell. There were no mortalities or embryos with edema, ascites or liver lesions in either treated group. No histological changes were observed in the livers or kidneys, however embryos exposed to 20 ul mineral oil had slight dilation of the heart. Body wt, liver wt, crown-rump length, and body wt/crown-rump length ratio of the embryos exposed to mineral oil did not differ from those of controls.

Mineral oil mists derived from highly refined oils and several formulated products appear to have a low acute and low sub-acute toxicity in animals. Single and short term repeated exposures (up to six months) to relative high conc (well in excess of 100 mg/cu m) have resulted in lung inflammatory reaction, lipoid granuloma formation, and lipoid pneumonia. /Oil mist, mineral/

[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1145]**PEER REVIEWED**

Long term inhalation studies indicate that those oils within a limited range which have actually been tested have a low chronic toxicity. ... Repeated prolonged exposures up to yr to very high conc (100 mg/cu m and above) have resulted in lung inflammatory reactions and lipoid granuloma formation. No carcinogenic effects have been reported in any species, including susceptible strains of mice. Adverse effects have not been found in long-term inhalation studies at lower oil mist conc more similar to actual workplace levels. /Oil mist, mineral/

[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1145]**PEER REVIEWED**

In groups of 30 rats of strains BDI, BD111, and W (sex unspecified) that received 2% liquid paraffin in the diet (total dose, 136 mg/animal in 500 days), no significant tumor induction was reported.

[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1145]**PEER REVIEWED**

... Three samples of petrolatum (snow-white U.S. Pharmacopeia (USP) XVI grade, white USP XVI grade, and yellow National Formulary XI grade) were fed at a conc of 5% in the diet to groups of 50 male and 50 female weanling rats (FDRL strain) for 2 years. None of the tests yielded a treatment-related tumor increase. /Oil mist, mineral/

[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I,II, III. Cincinnati, OH: ACGIH, 1991. 1145]**PEER REVIEWED**

Done 20 5
A group of 30 rats of strains BDI, BDII and W (sex unspecified) received 2% liquid paraffin in the diet (total dose, 136 ml/animal in 500 days); no significant tumor induction was reported.

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work).,p. V33 119 (1984)]**PEER REVIEWED**

Treatment of male Sherman rats thrice weekly by gavage with mineral oil at a dose of 2 ml/kg body weight for three months did not produce toxic effects.

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work).,p. V33 131 (1984)]**PEER REVIEWED**

000102

MINERAL OIL

CASRN: 8012-95-1

For other data, click on the Table of Contents

Pharmacology:

Therapeutic Uses:

IT HAS BEEN USED ORALLY TO LESSEN THE STRAIN OF EVACUATION OF INSPISSATED STOOL (...IN PATIENT WITH HERNIA OR CARDIOVASCULAR DISEASE) OR RECTALLY TO EASE PASSAGE OF IMPACTED OR DRIED FECAL MATERIAL.

[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 1307]**PEER REVIEWED**

/USED AS EMOLLIENTS IN BATH OIL/...HELPFUL IN ICHTHYOSIS OR PRURITIC & CHRONIC ECZEMATOUS DERMATOSIS.

[American Medical Association, AMA Department of Drugs. AMA Drug Evaluations. 4th ed. Chicago: American Medical Association, 1980. 1015]**PEER REVIEWED**

WHEN ADMIN ORALLY, MINERAL OIL & MINERAL OIL EMULSION PRODUCE LAXATION AFTER 6-8 HR.

[McEvoy, G.K. (ed.). American Hospital Formulary Service--Drug Information 94. Bethesda, MD: American Society of Hospital Pharmacists, Inc. 1994 (Plus Supplements). 1894]**PEER REVIEWED**

ALTHOUGH MINERAL OIL EMULSIONS PENETRATE & SOFTEN FECAL MATERIAL MORE EFFECTIVELY & ARE MORE PALATABLE THAN PLAIN MINERAL OIL, THERE APPEARS TO BE LITTLE DIFFERENCE IN LAXATIVE EFFECTIVENESS BETWEEN THESE TWO PREPARATIONS. ...MAY ALSO BE ADMIN RECTALLY AS AN ENEMA. PLAIN (NONEMULSIFIED) MINERAL OIL SHOULD BE ADMIN ONLY @ BEDTIME ON AN EMPTY STOMACH. ...EMULSION MAY BE ADMIN WITH MEALS. CONTAINERS OF MINERAL OIL EMULSIONS SHOULD BE SHAKEN BEFORE USING. DOSAGE OF...EMULSION IS EXPRESSED IN TERMS OF ITS MINERAL OIL CONTENT.

[McEvoy, G.K. (ed.). American Hospital Formulary Service--Drug Information 94. Bethesda, MD: American Society of Hospital Pharmacists, Inc. 1994 (Plus Supplements). 1894]**PEER REVIEWED**

In severe cases of constipation, such as with fecal impaction, mineral oil and stool softener laxatives administered orally or rectally are indicated to soften the impacted feces. To help complete the evacuation of the impacted colon, a rectal stimulation or saline laxative may follow.

[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1704]**PEER REVIEWED**

MEDICATION (VET): ORALLY, AS A LAXATIVE WITH LIGHT GRADES (LOW VISCOSITY) EVEN HAVING SOME ADVANTAGE IN ANIMALS OVER HEAVY GRADES (HIGH VISCOSITY).

[Rossoff, I.S. Handbook of Veterinary Drugs. New York: Springer Publishing Company, 1974. 366]**PEER REVIEWED**

000103

MEDICATION (VET): A preparation that contains 0.5% neomycin, 1% carbaryl, 9% sulfacetamide,

0.5% tetracaine, and 88.1% mineral oil is used in treatment of ear infections and ear mite infestations of small animals, including rabbits...

[Booth, N.H., L.E. McDonald (eds.). Veterinary Pharmacology and Therapeutics. 5th ed. Ames, Iowa: Iowa State University Press, 1982. 668]**PEER REVIEWED**

Increase water retention in the stool by coating surfaces of stool and intestines with a water-immiscible film. Lubricant effect eases passage of contents through intestines. Emulsification of lubricant tends to enhance its ability to soften stool mass.

[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1705]**PEER REVIEWED**

IT PENETRATES & SOFTENS THE STOOL; IT MAY ALSO INTERFERE WITH ABSORPTION OF WATER.

[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 1009]**PEER REVIEWED**

...PROMOTES BOWEL MOVEMENT BY RETARDING WATER REABSORPTION; THERE IS NO STIMULATION OF PERISTALSIS.

[Miller, R. R., and D. J. Greenblatt. Handbook of Drug Therapy. New York: Elsevier North Holland, 1979. 1057]**PEER REVIEWED**

MEDICATION (VET): TOPICALLY, IT HAS BEEN USED AS A VEHICLE IN OINTMENTS (INCL OPHTHALMIC), WOUND DRESSINGS, & INTRAMAMMARY PRODUCTS. ARGUMENTS AGAINST ITS USE IN THE LATTER HAVE BEEN BASED ON THE POTENTIAL CARCINOGENICITY OF CERTAIN GRADES (FOR THE CONSUMER OF MILK) OR DIFFICULTY OF ELIMINATING LAST FEW DROPLETS FROM MAN'S FOOD SUPPLY.

[Rossoff, I.S. Handbook of Veterinary Drugs. New York: Springer Publishing Company, 1974. 367]**PEER REVIEWED**

Drug Warnings:

...CAN CAUSE VARIETY OF UNTOWARD EFFECTS, & ITS USE AS A LAXATIVE REQUIRES APPRECIATION OF ITS POTENTIAL HAZARDS... HABITUAL USE OF MINERAL OIL MUST BE AVOIDED. ... INDISCRIMINATE USE...BY ELDERLY, DEBILITATED, OR DYSPHAGIC INDIVIDUALS SHOULD BE DISCOURAGED.

[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 1009]**PEER REVIEWED**

ORAL USE FOR MORE THAN TWO WEEKS COATS THE MUCOSA OF THE SMALL INTESTINE AND REDUCES THE ADSORPTION OF VITAMINS, ESPECIALLY THE FAT-SOLUBLE VITAMINS (A, D, E, AND K). THE PATIENT SHOULD BE WARNED THAT LIPID PNEUMONIA MAY OCCUR IF MINERAL OIL IS ASPIRATED AND THAT UNTOWARD EFFECTS, SUCH AS HEPATIC INFILTRATION, CAN RESULT FROM ITS ABSORPTION. BECAUSE OF THE THEORETICAL POSSIBILITY THAT CONCURRENT USE OF THE VARIOUS DETERGENT DOCUSATE SALTS MAY FURTHER ENHANCE THE ABSORPTION OF MINERAL OIL, THEIR CONCOMITANT ADMINISTRATION IS NOT RECOMMENDED.

[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 1307]**PEER REVIEWED**

000104

MINERAL OIL STILL PRESCRIBED BY SOME SURGEONS AFTER ANORECTAL SURGERY

<http://sis.nlm.nih.gov/cgi-bin/sis/search/1?/temp/~AAAVGUCG.1.prty>

1/19/00

DESPITE THE FACT THAT IT SOMETIMES CAUSES PRURITUS ANI, & LACERATION OF THE AREA FROM SCRATCHING OR RUBBING INTERFERES WITH HEALING.

[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 1308]**PEER REVIEWED**

In recent years, the oral use of mineral oil has not been advocated because of the possibility of interference with the absorption of fat-soluble vitamins and the danger of pulmonary aspiration. The dose required for the former effect exceeds that normally used in clinical practice. ... Oral mineral oil should not be given to patients with swallowing abnormalities.

[American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994. 951]**PEER REVIEWED**

Oral mineral oil is not recommended for bedridden elderly patients since they are more prone to aspiration of oil droplets, which may produce lipid pneumonia.

[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1705]**PEER REVIEWED**

Oral mineral oil is not recommended for children up to 6 years of age since patients in this age group are more prone to aspiration of oil droplets, which may produce lipid pneumonia.

[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1705]**PEER REVIEWED**

... The use of olive or mineral oil /for treating petroleum distillate poisoning is controversial. The oil is used to/ increase the viscosity, thereby decreasing the chance of aspiration if vomiting occurs after the initial ingestion. Such oil also acts as a cathartic to hasten the petroleum distillate from the gastrointestinal tract. however, if aspirated, the oil can cause lipid pneumonia. A 6 year retrospective study showed an increased incidence of pneumonia in children who were given oil, therefore the use of oils should be avoided.

[Haddad, L.M., Clinical Management of Poisoning and Drug Overdose. 2nd ed. Philadelphia, PA: W.B. Saunders Co., 1990. 1184]**PEER REVIEWED**

Interactions:

Concurrent use of /anticoagulants, coumarin- or indandione-derivative, oral, or contraceptive, oral, or digitalis glycosides or vitamins, fat-soluble, such as A, D, E, and K/ with mineral oil may interfere with the proper absorption of these or other medications and reduce their effectiveness.

[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1706]**PEER REVIEWED**

In addition to interfering with absorption of oral anticoagulants, mineral oil also decreases absorption of vitamin K, which may lead to increased anticoagulant effects.

[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1706]**PEER REVIEWED**

Concurrent use /with stool softener laxatives/ may cause increased absorption of mineral oil and result in the formation of tumor-like deposits in tissues.

[USP Convention. USPDI-Drug Information for the Health Care Professional. 14th ed. Volume I. Rockville, MD: United States Pharmacopeial Convention, Inc., 1994. (Plus Updates). 1706]**PEER REVIEWED**

Minimum Fatal Dose Level:

1= PRACTICALLY NON-TOXIC: PROBABLE ORAL LETHAL DOSE (HUMAN) ABOVE 15 G/KG, MORE THAN 1 QUART (2.2 LB) FOR 70 KG PERSON (150 LB).

[Gosselin, R.E., R.P. Smith, H.C. Hodge. Clinical Toxicology of Commercial Products. 5th ed. Baltimore: Williams and Wilkins, 1984.,p. II-156]**PEER REVIEWED**

MINERAL OIL

CASRN: 8012-95-1

For other data, click on the Table of Contents

Environmental Standards & Regulations:

FIFRA Requirements:

In 1988, Congress amended FIFRA to strengthen and accelerate EPA's reregistration program. The nine-year reregistration scheme mandated by "FIFRA 88" applies to each registered pesticide product containing an active ingredient initially registered before November 1, 1984. Pesticides for which EPA had not issued Registration Standards prior to the effective date of FIFRA '88 were divided into three lists based upon their potential for exposure and other factors, with List B being of highest concern and D of least. List: C; Case: Aliphatic solvents; Case No.: 3004; Pesticide type: Insecticide, Fungicide, Herbicide, Rodenticide, Antimicrobial; Case Status: Awaiting Data/Data in Review: OPP awaits data from the pesticide's producer(s) regarding its human health and/or environmental effects, or OPP has received and is reviewing such data, in order to reach a decision about the pesticide's eligibility for reregistration. Active Ingredient (AI): Mineral oil - includes paraffin oil from 063503; AI Status: The producer(s) of the pesticide has made commitments to conduct the studies and pay the fees required for reregistration, and is meeting those commitments in a timely manner.

[USEPA/OPP; Status of Pesticides in Reregistration and Special Review p.170 (Mar, 1992) EPA 700-R-92-004]**PEER REVIEWED**

For the purposes of this section, the insecticide mineral oil is defined as the refined petroleum fraction having the following characteristics: (1) minimum flashpoint of 300 deg F; (2) gravity of 27 to 34 by the American Petroleum Institute standard method; (3) pour point of 30 deg F maximum; (4) color 2 maximum by standards of the ASTM; (5) boiling point between 480 deg F and 960 deg F; (6) viscosity at 100 deg F of 100 to 200 seconds Saybolt; (7) unsulfonated residue of 90 percent minimum; and (8) no sulfur compounds according to the U.S. Pharmacopeia test under Liquid Petrolatum.

[40 CFR 180.149(a) (7/1/92)]**PEER REVIEWED**

Tolerances for residues of mineral oil as specified in paragraph (a) of this section are established in or on the following grains from postharvest application: shelled corn and grain sorghum.

[40 CFR 180.149(b) (7/1/92)]**PEER REVIEWED**

Residues of mineral oil are exempted from the requirement of a tolerance when used as a diluent, carrier, and solvent in accordance with good agricultural practices as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.

[40 CFR 180.1001(c) (7/1/92)]**PEER REVIEWED**

Mineral oil is exempted from the requirement of a tolerance when used as a solvent, diluent in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals.

[40 CFR 180.1001(e) (7/1/92)]**PEER REVIEWED**

FDA Requirements:

300107

White mineral oil is a food additive permitted for direct addition to food for human consumption, as long as 1) the quantity added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect in food, and 2) when intended for use in or on food it is of appropriate food grade and is prepared and handled as a food ingredient.

[21 CFR 172.878 (4/1/93)]**PEER REVIEWED**

Mineral oil is an indirect food additive for use only as a component of adhesives.

[21 CFR 175.105 (4/1/93)]**PEER REVIEWED**

Mineral oil may safely be used in animal feed, subject to the provisions of this section.

[21 CFR 573.680 (4/1/93)]**PEER REVIEWED**

Allowable Tolerances:

Tolerances of 200 ppm for residues of mineral oil as specified in paragraph (a) of this section are established in or on the following grains from postharvest application: shelled corn and grain sorghum.

[40 CFR 180.149(b) (7/1/92)]**PEER REVIEWED**

Residues of mineral oil are exempted from the requirement of a tolerance when used as a diluent, carrier, and solvent in accordance with good agricultural practices as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.

[40 CFR 180.1001(c) (7/1/92)]**PEER REVIEWED**

Mineral oil is exempted from the requirement of a tolerance when used as a solvent, diluent in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals.

[40 CFR 180.1001(e) (7/1/92)]**PEER REVIEWED**

MINERAL OIL

CASRN: 8012-95-1

For other data, click on the Table of Contents

Chemical/Physical Properties:

Molecular Formula:

UVCB

****PEER REVIEWED****

Color/Form:

COLORLESS, OILY LIQ

[Budavari, S. (ed.). The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals. Rahway, NJ: Merck and Co., Inc., 1989. 1139] ****PEER REVIEWED****

Colorless, oily liquid aerosol dispersed in air.

[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 94-116. Washington, D.C.: U.S. Government Printing Office, June 1994. 236] ****QC REVIEWED****

Odor:

Practically odorless even when warmed

[Budavari, S. (ed.). The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals. Rahway, NJ: Merck and Co., Inc., 1989. 1139] ****PEER REVIEWED****

Odor like burned lubricating oil.

[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 94-116. Washington, D.C.: U.S. Government Printing Office, June 1994. 236] ****QC REVIEWED****

Taste:

Practically tasteless even when warmed

[Budavari, S. (ed.). The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals. Rahway, NJ: Merck and Co., Inc., 1989. 1139] ****PEER REVIEWED****

Boiling Point:

360 DEG C

[National Fire Protection Association. Fire Protection Guide on Hazardous Materials. 7th ed. Boston, Mass.: National Fire Protection Association, 1978., p. 325M-146] ****PEER REVIEWED****

Density/Specific Gravity:

0.875-0.905 /heavy/

[Budavari, S. (ed.). The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals. Rahway, NJ: Merck and Co., Inc., 1989. 1139] ****PEER REVIEWED****

Solubilities:

INSOL IN WATER, ALCOHOL; SOL IN BENZENE, CHLOROFORM, ETHER, CARBON DISULFIDE, PETROLEUM ETHER

[Budavari, S. (ed.). The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals. Rahway, NJ: Merck and Co., Inc., 1989. 1139]**PEER REVIEWED**

MISCIBLE WITH MOST FIXED OILS; NOT MISCIBLE WITH CASTOR OIL; SOL IN VOLATILE OILS

[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 746]**PEER REVIEWED**

Surface Tension:

@ 25 DEG C SLIGHTLY BELOW 35 DYNES/CM

[Budavari, S. (ed.). The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals. Rahway, NJ: Merck and Co., Inc., 1989. 1139]**PEER REVIEWED**

Viscosity:

KINEMATIC VISCOSITY NOT LESS THAN 38.1 CENTISTOKES @ 37.8 DEG C

[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 746]**PEER REVIEWED**

Other Chemical/Physical Properties:

DEVELOPS NOT MORE THAN A FAINT ODOR OF PETROLEUM WHEN HEATED; FREE OR NEARLY FREE FROM FLUORESCENCE

[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 746]**PEER REVIEWED**

BURNED LUBE OIL ODOR /OIL MIST (MINERAL)/

[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values, 4th ed., 1980. Cincinnati, Ohio: American Conference of Governmental Industrial Hygienists, Inc., 1980. 314]**PEER REVIEWED**

Density: 0.83-0.860 /light/

[Budavari, S. (ed.). The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals. Rahway, NJ: Merck and Co., Inc., 1989. 1139]**PEER REVIEWED**

MINERAL OIL

CASRN: 8012-95-1

For other data, click on the Table of Contents

Manufacturing/Use Information:

Major Uses:

INGREDIENT IN VARIOUS PHARMACEUTICAL PREPARATIONS

[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 952]**PEER REVIEWED**

FORMERLY AS A VEHICLE FOR DRUGS TO BE APPLIED TO NASAL MUCOUS MEMBRANES /LIGHT/

[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 952]**PEER REVIEWED**

MEDICATION (VET)

PEER REVIEWED

MEDICATION

PEER REVIEWED

FLOOR TREATMENT

[Hawley, G.G. The Condensed Chemical Dictionary. 10th ed. New York: Van Nostrand Reinhold Co., 1981. 774]**PEER REVIEWED**

LUBRICANT IN MFR OF FOOD PRODUCTS

[Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Cleveland: The Chemical Rubber Co., 1972. 402]**PEER REVIEWED**

AS A VEHICLE TO DISSOLVE OR SUSPEND MEDICINAL AGENTS

[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 84:2408]**PEER REVIEWED**

AS DETERGENT FOR REMOVAL OF DERMATOLOGICAL PREPN /LIGHT/

[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 84:2408]**PEER REVIEWED**

IN CRACKING-FLOTATION METHOD OF GRAIN PRESERVATION

[White-Stevens, R. (ed.). Pesticides in the Environment: Volume 3. New York: Marcel Dekker, Inc., 1977. 269]**PEER REVIEWED**

IN FUNGICIDES

[White-Stevens, R. (ed.). Pesticides in the Environment: Volume 2. New York: Marcel Dekker, Inc., 1976. 90]**PEER REVIEWED**

IN INSECTICIDES; HERBICIDES /PETROLEUM OILS/

[Farm Chemicals Handbook 87. Willoughby, Ohio: Meister Publishing Co., 1987.,p. A-25]**PEER REVIEWED**

Superfating agent in soaps

[Kirk-Othmer Encyclopedia of Chemical Technology. 3rd ed., Volumes 1-26. New York, NY: John Wiley and Sons, 1978-1984.,p. V21 177]**PEER REVIEWED**

Liquid defoamer in papermaking

[Kirk-Othmer Encyclopedia of Chemical Technology. 3rd ed., Volumes 1-26. New York, NY: John Wiley and Sons, 1978-1984.,p. V16 807]**PEER REVIEWED**

Used in clear gel hair dressings

[Kirk-Othmer Encyclopedia of Chemical Technology. 3rd ed., Volumes 1-26. New York, NY: John Wiley and Sons, 1978-1984.,p. V12 95]**PEER REVIEWED**

Pharmaceutical preparations (processing aids, intestinal lubricants); cosmetics (cold creams, hair preparations); food applicants (release agents, binders, flotation sealants, defoamants, protective coatings); food packaging and processing; chemical and plastics industry (processing medium, extenders, plasticizers); and animal feed products /medical white oils/

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work).,p. V33 112]**PEER REVIEWED**

Cosmetics (hair oils, creams); textile-machine lubricants; horticultural sprays; wrapping paper; corrosion protection in meat-packing industry; and lubricants for watches, bicycles and spindles /technical white oils/

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work).,p. V33 112]**PEER REVIEWED**

Emollient in cosmetics

[Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present.,p. V7 586]**PEER REVIEWED**

Used in cosmetic molded sticks

[Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present.,p. V7 594]**PEER REVIEWED**

The classic cold cream consists of mineral oil (50-60%)...

[Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present.,p. V7 603]**PEER REVIEWED**

Hydraulic fluid for hydrostatic machines, e.g., machine tools, presses, and construction machinery...control plants, tippers and small loaders

[Gerhartz, W. (exec ed.). Ullmann's Encyclopedia of Industrial Chemistry. 5th ed. Vol A1: Deerfield Beach, FL: VCH Publishers, 1985 to Present.,p. A13 169]**PEER REVIEWED**

Liquid insulating material

[Gerhartz, W. (exec ed.). Ullmann's Encyclopedia of Industrial Chemistry. 5th ed. Vol A1: Deerfield Beach, FL: VCH Publishers, 1985 to Present.,p. VA14 360]**PEER REVIEWED**

Component of the...negative plate...of lead-acid batteries

[Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present.,p. V3 1095]**PEER REVIEWED**

MINERAL OIL IS COMBINED WITH PHENOLPHTHALEIN IN SOME MULTIPLE INGREDIENT

[Miller, R. R., and D. J. Greenblatt. Handbook of Drug Therapy. New York: Elsevier North Holland, 1979. 1057]**PEER REVIEWED**

IT IS USED AS "FOOD-SAFE" LUBRICANT ON PANS, ROLLERS, BELTS, & MACHINERY IN CLOSE PROXIMITY TO MANY FOODS, & AS A DEFOAMING AGENT IN FOODS. IT IS A COMMON OR MAIN INGREDIENT IN "BABY OILS" OR AGENTS USED TO IMPROVE SHEEN OF LIVESTOCK HAIR FOR SHOWS. APPARENTLY SUCCESSFUL AS THE MAIN INGREDIENT IN VIGOROUSLY APPLIED TOPICAL OILS FOR NON-SPECIFIC DERMATITIS OR SEBORRHEAS IN DOGS. TOPICALLY, AS A MITICIDE FOR SNAKES (BY IMMERSION), & AS AN INSECTICIDE ADJUVANT ON MANY CLASSES OF LIVESTOCK. IT HAS BEEN USED AGAINST EAR MITES. APPLIED TOPICALLY WITHIN THE CLOACA IT HAS BEEN OF VALUE IN EGG BOUND CAGED BIRDS. MORTALITY AND HYPERKERATOSIS ASSOCIATED WITH TOPICAL APPLICATION IN YOUNG CHICKS APPEARS TO BE SECONDARY TO MICROBIAL INFECTION. HAS BEEN USED AS A CAPILLARY SEAL FOR EGGS IN COLD STORAGE.

[Rossoff, I.S. Handbook of Veterinary Drugs. New York: Springer Publishing Company, 1974. 367]**PEER REVIEWED**

Methods of Manufacturing:

...BY REFINING CRUDER LUBRICATING OILS TO REMOVE UNSATURATED OR VOLATILE COMPOUNDS, AS WELL AS RESINS & COMPOUNDS OF NITROGEN & SULFUR. LIQUID PETROLATUM CONSISTS LARGELY OF SATURATED ALIPHATIC (C14 TO C18) & CYCLIC HYDROCARBONS.

[Gosselin, R.E., R.P. Smith, H.C. Hodge. Clinical Toxicology of Commercial Products. 5th ed. Baltimore: Williams and Wilkins, 1984.,p. II-156]**PEER REVIEWED**

AN OIL EITHER PRESSED OR DRY-DISTILLED FROM PARAFFIN DISTILLATE.

[Sax, N.I. and R.J. Lewis, Sr. (eds.). Hawley's Condensed Chemical Dictionary. 11th ed. New York: Van Nostrand Reinhold Co., 1987. 873]**PEER REVIEWED**

AFTER REMOVING THE LIGHTER HYDROCARBONS FROM PETROLEUM...THE RESIDUE IS AGAIN.../DISTILLED/ BETWEEN 330-390 DEG C & THE DISTILLATE TREATED FIRST WITH SULFURIC ACID, THEN SODIUM HYDROXIDE &...DECOLORIZED BY FILTERING... THE PURIFIED PRODUCT IS AGAIN CHILLED, TO REMOVE PARAFFIN, & REDISTILLED @ TEMP ABOVE 330 DEG C.

[Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980. 746]**PEER REVIEWED**

General Manufacturing Information:

A MIXTURE OF LIQUID HYDROCARBONS FROM PETROLEUM.

[Budavari, S. (ed.). The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals. Rahway, NJ: Merck and Co., Inc., 1989. 1139]**PEER REVIEWED**

LIGHT MINERAL OIL IS SIMILAR TO MINERAL OIL BUT LOWER MOLECULAR WEIGHT HYDROCARBONS PREDOMINATE, RESULTING IN LOWER VISCOSITY & SPECIFIC GRAVITY. /LIGHT MINERAL OIL/

[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 56:12]**PEER REVIEWED**

GRADES: BY VISCOSITY & COLOR.

[Sax, N.I. and R.J. Lewis, Sr. (eds.). Hawley's Condensed Chemical Dictionary. 11th ed. New York: Van Nostrand Reinhold Co., 1987. 873]**PEER REVIEWED**

OILS MAY CONTAIN TOCOPHEROL OR BUTYLATED HYDROXYTOLUENES TO INHIBIT OXIDATION. /HEAVY & LIGHT/

[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 56:12]**PEER REVIEWED**

/LIQUID PETROLATUM IS/ THE OFFICIAL USP NAME FOR A MIXTURE OF REFINED LIQ HYDROCARBONS OF HIGH VISCOSITY.

[Gosselin, R.E., R.P. Smith, H.C. Hodge. Clinical Toxicology of Commercial Products. 5th ed. Baltimore: Williams and Wilkins, 1984.,p. II-156]**PEER REVIEWED**

...IT HAS BEEN DIFFICULT FOR MANY TO ACCEPT WHEN THE UNITED STATES PERMITS ITS USE IN ANIMAL FEEDS TO REDUCE DUSTINESS OF FEEDS OR MINERAL SUPPLEMENTS; AS A LUBRICANT IN PRODUCING PELLETS, CUBES, BLOCKS; & TO PREVENT SEGREGATION OF TRACE MINERALS IN MINERALIZED SALT... US REGULATIONS SET A MAXIMUM OF 3.0% FOR...USE IN MINERAL SUPPLEMENTS & 0.06% OF THE TOTAL RATION WHEN USED IN FEED OR FEED CONCENTRATES.

[Rossoff, I.S. Handbook of Veterinary Drugs. New York: Springer Publishing Company, 1974. 367]**PEER REVIEWED**

IN REFINEMENT FOR HUMAN USE, AROMATIC AMINES & UNSATURATED HYDROCARBONS ARE REMOVED FROM PETROLEUM, LEAVING A VARIETY OF SATURATED HYDROCARBONS. PALATABILITY...IS IMPROVED WHEN IT IS EMULSIFIED WITH ACACIA.

[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 56:12]**PEER REVIEWED**

PESTICIDE TOLERANCES & EXEMPTIONS FOR POSTHARVEST USE ON GRAIN CROPS: PESTICIDE TOLERANCES IN PPM: MINERAL OIL: 200 PPM ON CORN & GRAIN SORGHUM. /FROM TABLE/

[White-Stevens, R. (ed.). Pesticides in the Environment: Volume 3. New York: Marcel Dekker, Inc., 1977. 304]**PEER REVIEWED**

Formulations/Preparations:

MINERAL OIL, USP (LIQUID PETROLATUM), IS AVAILABLE IN NUMEROUS PREPN, OFTEN UNDER VARIOUS TRADE NAMES.

[Gilman, A. G., L. S. Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980. 1009]**PEER REVIEWED**

AGORAL, PLAIN (PARKE, DAVIS), FLEET MINERAL OIL ENEMA (FLEET), KONDREMUL PLAIN (FISONS), PETROGALAR, PLAIN (WYETH) (ALL NONPRESCRIPTION).

[American Medical Association, AMA Department of Drugs. AMA Drug Evaluations. 5th ed. Chicago: American Medical Association, 1983. 1308]**PEER REVIEWED**

DOMOL (DOME), LUBATH (WARNER/LAMBERT), SURFOL (STIEFEL).

[American Medical Association, AMA Department of Drugs. AMA Drug Evaluations. 4th ed. Chicago: American Medical Association, 1980. 1015]**PEER REVIEWED**

JELLY, ORAL, 55% WEIGHT/WEIGHT (NEO-CULTOL); OIL (NUJOL); OIL, RECTAL (FLEET MINERAL OIL ENEMA); SUSPENSION, ORAL 1.6 ML/5 ML (AGORAL PLAIN); 2.75 ML/5 ML (KONDREMUL PLAIN EMULSION) & 3.25 ML/5 ML (PETROGALAR PLAIN). /MINERAL OIL, HEAVY/

[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 56:12]**PEER REVIEWED**

OIL, RECTAL (SAF-TIP OIL RETENTION ENEMA); OIL (AVAILABLE BY NONPROPRIETARY NAME). /MINERAL OIL, LIGHT/

[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 56:12]**PEER REVIEWED**

Medical /and technical/ white oils may contain alpha-tocopherol (Vitamin E) at levels up to 10 mg/kg as an antioxidant

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work).,p. V33 94 (1984)]**PEER REVIEWED**

Impurities:

Polynuclear aromatic compounds have been detected in samples of mineral oil for medicinal and cosmetic uses

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work).,p. V33 94 (1984)]**PEER REVIEWED**

U. S. Imports:

(1984) 1.69X10+7 g

[BUREAU OF THE CENSUS. U.S. IMPORTS FOR CONSUMPTION AND GENERAL IMPORTS 1984 p.1-386]**PEER REVIEWED**

U. S. Exports:

(1984) 7.49X10+7 g /medicinal and non-medicinal/

[BUREAU OF THE CENSUS. U.S. EXPORTS, SCHEDULE E, 1984 p.2-63 and 2-65]**PEER REVIEWED**

End Submission

Reference List for Industry Submission, GRN 000040

<i>Pages</i>	<i>Author</i>	<i>Title</i>	<i>Publish Date</i>	<i>Publisher</i>	<i>BIB_Info</i>
000021 - 000022	NA	Monograph Specifications: Mineral Oil, White	NA	Food Chemicals Codex	4th Edition, pgs 256-257
000034 - 000039	Bohn, Raymond T.	A Thorough Discussion of White Mineral Oil in the Baking Industry	October 1960	Cereal Science Today	Volume 5, Number 8, pgs 234 - 238
000083 - 000084	Baldwin, M. K.; Berry, P. H.; Esdaile, D. J.; Linnett, S. L.; Martin, J. G.; Peristianis, G. C.; Priston, R. A.	Feeding studies in rats with mineral hydrocarbon food grade white oils	1992	Toxicol Pathol	Volume 20, Issue 3, Part 1, pgs 426 - 435
000085	Smith, J. H.; Bird, M.G.; Lewis, S. C.; Freeman, J. J.; Hogan, G. K.; Scala, R. A.	Subchronic Feeding Study of Four White Mineral Oils in Dogs and Rats	1995	Drug and Chemical Toxicology	Volume 18, Number 1, pgs 83 -103
000086	Fleming, K. A.; Zimmerman, H.; Shubik, P.	Granulomas in the livers of Humans and Fischer rats associated with the ingestion of mineral hydrocarbons a comparison	1998	Regul Toxicol Pharmacol	Volume 27, Issue 1, Part 1, pgs 75 - 81
000087 - 000088	Smith, J. H.; Mallett A. K. ; Priston, R. A.; Brantom, P. G.; Worrell, N. R.; Sexmith, C.; Simpson, B. J.	Ninety day feeding study in Fischer 344 rats of highly refined petroleum derived food grade white oils and waxes	1996	Toxicol Pathol	Volume 24, Issue 2, pgs 214 - 230
000089 - 000090	Nash, J. F.; Gettings, S. D.; Diembeck, W.; Chudowski, M.; Kraus, A. L.	A toxicological review of topical exposure to white mineral oils	1996	Food Chem Toxicol	Volume 34, Issue 2, pgs 213 - 225
000091	Shoda, T.; Tosyoda, K.; Uneyama, C.; Takada, K.; Takahashi, M.	Lack of carcinogenicity of medium-viscosity liquid paraffin given in the diet to F344 rats	1997	Food Chem Toxicol	Volume 35, Issue 12, pgs 1181 - 1190
000092	Miller, M. J.; Lonardo, E. C.; Greer, R. D. ; Bevan, C.; Edwards, D. A.; Smith, J. H.; Freeman, J. J.	Variable responses of species and strains to white mineral oils and paraffin waxes	1996	Regul Toxicol Pharmacol	Volume 23, Issue 1, Part 1, Pgs 55 - 68

NA- Not applicable